

**EFFECTIVENESS OF INTRADIALYTIC STRETCHING
EXERCISES ON PREVENTION AND REDUCTION OF MUSCLE
CRAMPS AMONG PATIENTS UNDERGOING
HAEMODIALYSIS AT PSG HOSPITALS COIMBATORE**



**By
LEKHA .J**

A dissertation submitted to **The Tamil Nadu Dr. M G R Medical University,**
Chennai, in partial fulfillment of requirement of the degree of

**Master of Science in Nursing
Branch I Medical Surgical Nursing**

2016

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CERTIFICATE

Certified that **"EFFECTIVENESS OF INTRADIALYTIC STRETCHING EXERCISES ON PREVENTION AND REDUCTION OF MUSCLE CRAMPS AMONG PATIENTS UNDERGOING HAEMODIALYSIS AT PSG HOSPITALS COIMBATORE"** is the bonafide work of **LEKHA .J**, PSG College of Nursing, Coimbatore, submitted in partial fulfillment of requirement for the degree of Master of Sciences in Nursing to **The Tamil Nadu Dr. M G R Medical University, Chennai.**

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ABSTRACT

Effectiveness of intradialytic stretching exercises on prevention and reduction of muscle cramps among patients undergoing haemodialysis at psg hospitals Coimbatore.

It is estimated that 33 to 86% of patients experience muscle cramps during haemodialysis, which results in early termination of haemodialysis session.

Objective of the Study:

1. Evaluate the effect of intradialytic stretching exercises on muscle cramps during haemodialysis

Research Methodology:

The study was conducted in PSG Hospitals, Coimbatore and the research design adopted was Quasi experimental Pre test Post test with comparison group. As per the inclusion criteria, 60 samples were selected and 30 each in both intervention and comparison group. On the day of first sitting of haemodialysis, the pre test score of muscle cramps was assessed by a standardized cramp questionnaire chart and the visual analogue scale. Intradialytic stretching exercises was given to the intervention group and the post test assessment was done on the day of 4th, 7th and 10th day of sitting by using the same tool.

Major Findings of the Study:

The intervention group revealed a reduction in the level of muscle cramps during haemodialysis after performing the intradialytic stretching exercises. While Comparing the intradialytic stretching exercises and the routine therapy there was a significant difference in the level of muscle cramps during the post test III. The results describes there is an effectiveness in the prevention and the reduction of muscle cramps during haemodialysis after 6 days of therapy.

Conclusion:

This study review showed that intradialytic stretching exercises helps to prevent and reduce the muscle cramps during haemodialysis.

Key words:

Intradialytic; Muscle cramps; Intradialytic stretching exercises; Routine care

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CHAPTER I

INTRODUCTION

1.1 Background of the study:

Haemodialysis is a life saving measure for patients with chronic kidney disease. Haemodialysis is an ongoing process where patients experience complications such as hypotension, muscle cramps, disequilibrium syndrome and nausea during the procedure. It is estimated that 33 to 86% of patients experience muscle cramps during haemodialysis, which results in early termination of haemodialysis session. There is a need for special attention for diagnosis and management of muscle cramps during haemodialysis to avoid the need for termination of the haemodialysis procedure.

Chronic kidney disease (CKD) has been increasingly recognized as a global health burden. Individuals with CKD are at risk for progressive loss of kidney function and kidney failure. One of the most common treatment for kidney failure is haemodialysis. Worldwide statistics shows that 9,20,000 people are undergoing haemodialysis per day, which constitutes about 7-8% of the total population (**Stephanie Titze et al., 2015**). The beginning and ending supportive therapy for the kidney failure is haemodialysis. (**Robert A Star, 2012**).

The 2010 global ranking of premature causes of death show that kidney diseases moved up from position 32 in 1990 to position 24 in 2010 (**C. G. Okwuonu et al., 2015**). Indian government has included kidney disease as a priority area and is setting up facilities to provide subsidized dialysis for the whole population. It is estimated that there are about 55,000 patients on dialysis in India and the dialysis population is growing at the rate of 10-20% annually.

Haemodialysis is an epoch-making medical technology introduced clinically in the early 1960's which made it possible to prolong the lives of patients with chronic kidney disease. Haemodialysis is usually done for twice or thrice in a week with each session lasting about four or six hours. The patient quality of life can be promoted and

the complications of renal failure can decrease with sufficient and effective haemodialysis (**Monfared et al., 2009**).

Muscle cramps (involuntary muscle contraction associated with severe pain) occur frequently in patients receiving dialysis. Muscle cramps can involve the legs, most commonly in the feet, but can also involve arms and hands, as well as abdominal muscles (**Holley, 2012; Kobrin & Berns, 2007**). Muscle cramps begin with fasciculations or muscle twitches and are felt to be related to nerve conduction rather than the muscles themselves (**Holley, 2012**).

Numerous factors are influencing the muscle cramps in patients undergoing haemodialysis which includes volume contraction, hypotension, changes in plasma osmolality, hyponatremia, tissue hypoxia, hypomagnesemia, deficiency of carnitine and elevated serum leptin (**Holley, 2012; Kobrin & Berns, 2007**).

The most common factors related to the haemodialysis procedure are volume depletion and hyponatremia. Preventing hypotension associated with dialysis, minimizing interdialytic weight gains, increasing the frequency of haemodialysis, have been effective in reducing the frequency of cramps. (**Holley & Sheon, 2011**)

Non- pharmacological therapy forms the cornerstone of the management of muscle cramps. It is important to discuss non-pharmacologic strategies to prevent and treat muscle cramps with patients in order to minimize pharmacotherapy. Local massage of the affected muscle and the application of moist heat may provide some comfort.

A trial of stretching program is a measure that can be done both for nocturnal leg cramps and for haemodialysis-related cramps triggered by the relaxation of the foot and ankle muscles from the prolonged recliner position for the dialysis treatment. Stretching is usually a first-line treatment for cramps, and pre-bedtime stretching has been seen as an easy treatment to decrease or eliminate nocturnal cramps (**Hallegraeff et al., 2012**). Nephrology/Dialysis nurses are in a unique position to help monitor and evaluate cramp prevention and management techniques.

1.2 Need for the study:

Muscle cramps are a common discomfort experienced by patients undergoing haemodialysis which is characterized by a sudden, painful, involuntary contraction of a muscle which originates from the peripheral nerves. The most commonly affected muscles are the gastrocnemius (calf muscles), triceps (the muscles in the upper arms), the hamstrings (the muscles behind the thighs), and the quadriceps (the muscles in front of the thighs). Many non pharmacologic therapies are employed by patients prior to treatment, but there is only a little evidence to support the use of non pharmacological measures.

There are different therapies like flexibility exercises and strengthening exercises to improve the physical functioning of the patient. Leg stretch exercises done during the dialysis procedure like quadriceps knee strengthening exercise, hamstring exercise and gluteal strengthening exercise will improve the muscle protein synthesis and breakdown, which helps in determining both strength and overall function of the body. **(Manisha Jhambe, Steven D Weisbord, Jennifer L Steel, Mark Unruh, 2008).**

The health benefits of stretching are amazing as it can increase stamina, relax body and mind, improve focus and concentration, and reduce the risk of injury. Other benefits of stretching exercises are reduction of stress and tension, muscle pain, soreness and increase flexibility and suppleness. It makes muscles more elastic and reduces the risk of injury. Stretching exercise can lower the build-up of lactic acid in muscles and eliminate tightness and any chance of damage. **(Kathleen Mccann, Jeniffer. R.P. Boore, 2000)**

Almost all patients complain of muscle cramps during dialysis. They are managed with normal saline and dextrose 25% routinely in hospital. Prophylactic stretching exercises can prevent the muscle cramps. The patients can practice stretching exercises during the post dialysis period.

It is important to discuss non-pharmacologic strategies to prevent and treat muscle cramps with patients in order to minimize pharmacotherapy and to utilize hemodialysis interventions such as sodium modeling and reassessing dry weight. The literature

describing effective pharmacotherapeutic interventions to prevent muscle cramps in patients with chronic kidney disease is lacking. Patient education about the available evidence for benefit and potential for harm of pharmacotherapy, is an important aspect of treatment.

Performing stretching exercises before dialysis, performing mild exercise such as riding a stationary bicycle during dialysis prevent cramps. Local heat (including showers or baths) or ice, massage, walking or leg jiggling followed by leg elevation, are other methods reported to help relieve muscle cramps (**Holley, 2012; Sheon, 2012**).

Exercises are very important element in the overall health of people at any age. Stretching exercises are the best measure to reduce or prevent cramps from occurring during haemodialysis among chronic renal failure patients (**Magda Mohamed, Amal Mohamed, Shalabia Abo Zead, 2007**).

A study found an association between the use of vitamin E, Vitamin C and the muscle cramps for the patients undergoing haemodialysis. A total of 60 haemodialysis patients with a mean of 4.4 cramps per week were randomized to receive vitamin E 400 IU daily, vitamin C 250 mg daily, a combination, or placebo for eight weeks. The mean number of cramps per week decreased by 54%, 61%, 97% and 7% for the vitamin E, vitamin C, combination and placebo groups respectively. But the adverse effects of Vitamin E is known to cause bleeding, and to interact with Warfarin to increase the risk of bleeding and vitamin c can result in the accumulation of a metabolite called oxalate. High levels of oxalate in the blood may lead to the development of kidney stones. (**Khajehdehi, Mojerlou, Behzadi, Rais Jalali, 2001**). A meta analysis of 19 clinical trials with 135,967 participants in studies of vitamin E found that high-dosage ($> \text{or } = 400 \text{ mg}$) causes increased mortality (**Miller, et al., 2005**).

A randomized controlled trials of non drug, non invasive intervention study for lower limb muscle cramps was conducted. Participants of age 60 years or over and had received a repeat prescription of quinine for night time cramps in the preceding three months were selected. Forty nine participants were advised to lean wall calf muscle stretching held for 10 seconds three times per day. Forty eight participants were allocated

to a placebo stretching group. After 12 weeks there was no significant adverse effect was reported. This study concluded that there is an urgent to evaluate the commonly recommended and emerging non drug therapy (**Blyton F, 2012**).

Regular physical activity can reduce the complications associated with CKD by inducing adaptations in the cardiovascular, nervous, and musculoskeletal systems. This increases the functional capacity and enhances quality of life in patients on HD. Haemodialysis patients can safely participate in a variety of exercise programs with minimal adverse effects. Intradialytic exercise programs that can incorporate aerobic and resistance exercise that promote exercise adherence and should be encouraged on dialysis units. (**Brenner I, 2009**).

Interventions during haemodialysis sessions have become more popular and have been shown to be safe. The risks of exercise in this population have not been rigorously studied, but there have been no reports of serious injury as a result of participation in an exercise training program. It is time that we incorporate exercise into the routine care of patients who are on dialysis (**Johansen .KL, 2007**).

The National Kidney Foundation of Italy recommended counseling by nephrologists to increase patients levels of physical activity in their guideline about management of cardiovascular disease. The guideline focused on well-being and functional capacity of renal patients. Patients should be counseled and encouraged by nephrology and dialysis staff to increase their level of physical activity. (**Aucella F, Valente. G.L, 2014**).

A telephone survey was conducted in Australia and found that intradialytic exercise programs are essentially nonexistent and there is a lack of randomized, controlled trials of intradialytic exercise training. The study concluded that there is a need of intradialytic stretching exercises for haemodialysis patients ,which may influence the current standard clinical practice among nephrologists and thus improve the health and quality of life of the vulnerable patients. (**Cheema. B.S, Smith. B.C, Singh. M.A, 2005**).

Staff in dialysis unit have a crucial role to encourage and assist patients during intra-dialysis exercise, but other professionals should be included in the ideal

"exercise team" for dialysis patients. In this scenario, dialysis nurses play a pivotal role since they guarantee a constant and direct approach. (Capitanini .A, et al., 2014).

Muscle cramps reduce quality of life, sleep and participation in activities of daily living. Many interventions are available for lower limb cramps but some are controversial and no treatment guidelines exist and often people experience no benefit from the interventions prescribed. Hence there is a need to practice some interventions for muscle cramps during haemodialysis. Intradialytic stretching exercises helps to improve the efficacy of haemodialysis thus preventing or reducing the muscle cramps.

1.3 Statement of the problem:

Effectiveness of intradialytic stretching exercises on prevention and reduction of muscle cramps among patients undergoing haemodialysis at PSG hospitals Coimbatore.

1.4 Objectives:

- Assess the level of muscle cramps among patients undergoing haemodialysis.
- Evaluate the effect of intradialytic stretching exercises on muscle cramps during haemodialysis
- Compare the effectiveness of intradialytic stretching exercises on prevention and reduction of muscle cramps between intervention group and comparison group.
- Determine the association between selected demographic variables with muscle cramps among patients undergoing haemodialysis.

1.5 Assumptions:

- Muscle cramps reduce the efficacy of haemodialysis.
- Muscle cramps limit a patient's ability to tolerate the complete session of haemodialysis.
- Exercises restores blood flow and relaxes the muscle tightness.
- Intradialytic stretching exercises helps to reduce the discomfort related to muscle cramps during haemodialysis.

1.6 Hypothesis:

There will be a significant reduction in the level of muscle cramps among intervention group receiving intradialytic stretching exercises.

1.7 Delimitations:

In this study the intradialytic stretching exercises were limited only to the lower limb cramps.

1.8 Operational definitions:

Effectiveness:

It refers to the reduction in the muscle cramps after administration of stretching exercises which is measurable by a cramp questionnaire chart and visual analogue scale.

Intradialytic:

Intradialytic refers to the period from the end of second hour after starting haemodialysis.

Intradialytic stretching exercises:

Intradialytic stretching is a form of physical exercise in which the calf, gastrocnemius, soleus, hamstring and quadriceps muscles are flexed or stretched to improve the muscle's elasticity, muscle tone and reduce the cramps during haemodialysis at a frequency of twice per sitting between 3rd and 4th hour for every 30 minutes.

Routine care:

In this study routine care refers to the administration of dextrose 25% during the intradialytic period.

Muscle Cramps:

Muscle cramps in this study refers to painful involuntary muscle contraction felt in the calf, gastrocnemius, soleus, hamstring and quadriceps muscles of the patients undergoing haemodialysis.

1.9 Projected outcome:

Intradialytic stretching exercises could prevent and reduce the muscle cramps among patients undergoing haemodialysis.

1.10 Conceptual framework:

Modified Wiedenbach's helping art of clinical nursing theory is used as the conceptual framework to assess the effectiveness of intradialytic stretching exercises on prevention and reduction of muscle cramps among patients undergoing haemodialysis

The conceptual framework was developed by Ernestine Wiedenbach in 1964. The theory has two parts (a) helping art of clinical nursing theory and (b) nursing practice. Helping art of clinical nursing theory is a prescriptive theory for nursing which describes a desired action and the ways to attain it. It consists of three factors, central purpose, prescription, and realities.

Central purpose: It refers to what the researcher wants to accomplish. It is the overall goal. It is the task or the assignment directing towards the attainment of goal and knowledge on intradialytic stretching exercises and the skill in performing intradialytic stretching exercises during haemodialysis.

The central purpose of the study is the prevention and the reduction of muscle cramps after giving intradialytic stretching exercises.

Prescription: It is the plan of care for a patient. It includes the action and the rationale for that action which fulfils the central purpose.

In this study intradialytic stretching exercises was used for the treatment group as a procedure. The procedure was done for 30 minutes and the muscle cramps were assessed using the muscle cramp questionnaire chart and the visual analogue scale.

Realities: It refers to the physical, physiological, emotional and spiritual factors that involves in nursing actions. There are five realities they are as follows.

Agent: One who directs all actions towards the goal and has capacities, capabilities, commitment and competence to provide care.

In this study the researcher is the agent who directs the action towards the goal.

Recipient: One who is vulnerable and dependent and receives all attention.

In this study the patients who are undergoing haemodialysis experiencing muscle cramps.

Goals: It refers to the desired outcome of the action. Prevention and reduction of the muscle cramps is the goal need to be attained.

Means: It refers to the activities used to achieve the goal. In this study intradialytic stretching exercises is given to the patients undergoing haemodialysis to prevent and reduce the muscle cramps.

Framework: It refers to the facilities in which it is practiced. It refers to the dialysis unit of PSG hospitals, Coimbatore.

Wiedenbach's nursing practice consists of identification, ministration and validation.

Identification: It refers to the individual unique experiences and the perceptions. In this study it refers to the selection of the samples and the assessment of muscle cramps.

Ministration: It refers to the provision of needed help.

Here it refers to the administration of intradialytic stretching exercises to the intervention group and the routine care to the comparison group.

Validation: Evaluating the patient after performing intradialytic stretching exercises for reduction in the level of muscle cramps during the haemodialysis.

In this study the assessment of muscle cramps before and after administering the intradialytic stretching exercises helps to validate.

CHAPTER II

REVIEW OF LITERATURE

A literature review helps to lay the foundation and provide context for a new study. An entire chapter often is devoted to a literature. The literature review is designed to appraise a body of research. Reviewing the literature can help to identify the relevant conceptual frameworks or appropriate research methods (**Polit, 2009**)

2.1 Literature related to prevalence of chronic kidney disease

2.2 Literature related to intradialytic resistance exercises on patients undergoing haemodialysis.

2.3 Literature related to intradialytic stretching exercises on muscle cramps.

2.1 Literature related to prevalence of chronic kidney disease

A screening was done to study the prevalence of CKD among adults in a rural population near Shimoga, Karnataka. Among 2091 people the dipstick proteinuria and serum creatinine was measured. It was found that the prevalence of proteinuria was 2.8% and the CKD was 16.54%.The study concluded that the prevalence of CKD is higher in rural population when compared to the urban population (**P.P Varma, 2015**).

A cross sectional study was done in New Delhi among central government employees over 18 years of age to estimate the prevalence of early stages of CKD using the kidney disease quality outcomes initiative. Among 3398 participants the serum creatinine ratio and the GFR rate was measured. It was found that the prevalence of CKD stage 1,2 was 13-15.04% and 3 as 6.62%, 5.40% and 3.02% respectively (**P.P Varma, 2015**).

An epidemiological study of Chronic kidney disease was undertaken in Abu Dhabi among 331,360 samples from 212,314 individuals to determine the prevalence of CKD patients. Based on serum creatinine and the GFR rate the CKD was identified. The mean serum creatinine was $61 \pm 48 \mu\text{mol/L}$ in females ($59 \pm 43 \mu\text{mol/L}$ in Emiratis, $63 \pm 54 \mu\text{mol/L}$ in expatriates) and $87 \pm 69 \mu\text{mol/L}$ in males ($80 \pm 59 \mu\text{mol/L}$ in Emiratis, $92 \pm$

74 $\mu\text{mol/L}$ in expatriates). Among Emiratis, 4.6% of males and 2.8% of females had an GFR between CKD stage 3 and 5. Among expatriates, 4.2% of males and 3.2% of females had an GFR between CKD stage 3 and 5. This study has defined the prevalence of CKD within Abu Dhabi and demonstrated the need to improve identification and referral of CKD patients **(Richards. N, Hassan. M, Saleh .A.K, 2015).**

An epidemiological study was conducted to determine the prevalence of chronic kidney disease and incidence of acute kidney injury (AKI) in patients with coronary artery disease (CAD) demonstrated on coronary angiography among 125 patients in Lilavati Hospital and Research Centre, Mumbai. All the patients were evaluated for Serum creatinine, routine urine analysis, and spot urine for protein to creatinine ratio. The study concludes that there is a very high prevalence of CKD (39.2%) in patients with chronic kidney disease and (38.4%) patients with acute kidney injury. The study suggested for nephrology referral in patients with abnormal urinalysis, spot urinary protein to creatinine ratio and in patients whose creatinine clearance is <60 ml/min **(Malleshappa. P, Shah. B.V, 2015).**

A survey was conducted in the urban and semi urban population of Delhi to determine the prevalence of patients with 3rd stage of chronic kidney disease. In the screened population there were 31.2% hypertensives and 7.3% diabetes mellitus. All the subjects underwent dipstick proteinuria and GFR calculation. The survey concluded that 4.2% of population is suffering from stage 3 CKD **(Singh, et al., 2012).**

2.2 Literature related to intradialytic resistance exercises on patients undergoing hemodialysis

A quasi-experimental study was conducted to compare the effects of active and passive intradialytic pedaling exercises among haemodialysis patients in the dialysis center of Akhavan Hospital, Iran. This study was performed on 18 patients for 8 months. All patients were dialyzed using high-flux dialyzer membranes for the first 8 weeks. Afterwards, for eight weeks, the patients received the passive intradialytic exercise using the electrically powered Mini-Bike adapted to the patient's bed for 30 minutes per session during the first 2 hours of dialysis session. After 8 weeks the active intradialytic pedaling

exercise was performed similarly for eight weeks. Paired t-test and the Wilcoxon signed rank and Friedman tests were used to compare the variables. The results found that the mean diastolic blood pressure was significantly decreased after the passive exercise ($P = 0.039$) and QOL was 63.78 ± 21.15 at the beginning of the study, which was increased to 77.07 ± 21.14 after performing the intradialytic exercise ($P = 0.007$). The study concluded that both the exercise programs improve the quality of life among haemodialysis patients **(Azra Sadat Musavian, et al., 2015)**.

A randomized controlled study was done in North Wales, UK to examine the impact of a novel intra-dialytic progressive resistance exercise training (PRET) program on muscle volume, strength, and physical function in HD patients as well as in non-HD healthy patients. In this single-blind controlled study, 23 HD and 9 non-HD patients were randomized to PRET, which consisted of thrice-weekly high-intensity leg press exercises and control (SHAM) therapy, which consisted of low-intensity lower body stretching activities using ultra-light resistance bands. After a 12-week interventional period, PRET resulted in a significant increase in the muscle volume with the mean difference [95 % CI]: $193[63 \text{ to } 324] \text{ cm}^3$ at $p=0.007$ compared to healthy SHAM (mean difference [95 % CI]: $169[-41 \text{ to } 379] \text{ cm}^3$ at $p=0.1$). Patients undergone SHAM therapy in the HD group, experienced clinically significant amounts of muscle volume loss **(Kirkman, et al., 2014)**.

A quasi experimental study was conducted in University of Thessaly, Larissa, Greece to determine the effect of prolonged intradialytic exercise in haemodialysis efficiency indices. Ten stable high-functioning haemodialysis patients were performed supine exercise (cycling) for 3 hours at 40% of maximum exercise capacity and no exercise as usual. Blood sampling was acquired pre- and post- haemodialysis in both scenarios to calculate the HD efficiency indices. All patients were completed the exercise regimen without adverse effects. The urea reduction ratio, and creatinine reduction ratio significantly improved by 20%, 11%, and 26%, respectively, while potassium plasma levels were reduced by 77.5% ($p < 0.05$). The results concluded that prolonged low-intensity intradialytic exercise improved HD efficiency, with no adverse effects **(Giannaki CD, et al., 2013)**.

A stepped wedge randomised control study was conducted in Deakin University to examine the effect of an coordinated resistance exercise on physical function among haemodialysis patients. An exercise program was implemented among 180 participants for 12, 24 or 36 weeks. The participants need to perform leg abduction, plantar flexion, dorsi flexion, straight-leg, bent-knee raise, knee extension and knee flexion in a seated position for 15–20 repetitions in each exercise. The standard α value of the three tests were ($p < 0.05$) was divided by three $\alpha = 0.0167$. The study concluded that there is an improvement in the physical function of people with end stage kidney disease who are receiving haemodialysis **(Paul N Bennett et al., 2013)**.

An open randomized controlled trial was done in dialysis center of Imman Khomeini hospital in Sari, Iran to determine the impact of an 8-week intradialytic exercise program on dialysis efficacy. Among 50 patients there were two groups which comprises of aerobic exercise group ($n=25$) and the control group ($n=25$). Aerobic exercises were done in the intervention group for 15 min/day, three times a week for 2 months. The dialysis efficacy was assessed prior to and at the end of each month of the program by measuring the urea concentrates and urea kinetics. It was found that values of the variables increased by 11% in URR ($p=0.003$) and 38% in $spKt/V$ ($p=0.001$) at the 8th week post-treatment in the intervention group. The study concluded that simplified aerobic exercise program has increased the efficacy of dialysis and considered as a safe, complementary and effective modality for haemodialysis patients **(Mohseni.R,et al., 2013)**.

An open label randomized controlled trial was done in Laennec and Confluent dialysis unit of the ECHO dialysis Association to analyze the impact of a progressive intra-dialytic exercise program combined with nutritional support to evaluate the functional performance, body composition and health-related quality of life in HD patients. A six-month adapted rehabilitation program was conducted among 210 patients undergoing haemodialysis by means of progressive submaximal individualized cycling exercise, consisting of three sessions per week. The exercise was prescribed during the first two hours of dialysis session using an adapted cycle ergometer 30 min duration of continuous cycling at a moderate exercise intensity. The results concluded that there was

a statistically significant difference in the effects of exercise to reverse the poor functional performance. For each analysis, the level of significance was $p < 0.05$ (**Justine Magnard, et al., 2013**).

A randomised controlled trial study was conducted at the Launceston General Hospital and Burnie Satellite Renal Units in Northern Tasmania and the Hobart Renal Unit which, combined service a population of approximately 485,000. The objective of the study was to compare the effects of supervised intradialytic and home-based exercise training on physical function and arterial stiffness among haemodialysis patients. Intradialytic training was administered during the first two hours of each dialysis session, three times per week for 6 months. Home-based participants were asked to perform unsupervised walking for six months two hours of each dialysis session, three times per week for 6 months. Power output (w) and duration (minutes) of each exercise session were recorded to estimate the participants' individual energy expenditure per session during the training period. The results explains that there is 10% improvement in 6 MWD which is statistically significant $p < 0.05$ ($\alpha = 0.05$, and $\beta = 0.9$) (**Kirsten P Koh, et al., 2009**).

A randomized controlled trial was conducted in the dialysis unit of a Brazilian University hospital to compare the effects of combined resistance and aerobic exercise with a resistance programme on functional performance among haemodialysis patients. Thirteen patients were allocated for each group of intervention. The patients were assigned to receive the resistance exercise combined with an aerobic training or to maintain an ongoing resistance programme alone for a period of 10 weeks. The functional performance of patients was assessed before and after the intervention through the 6-minute walk test (6MWT). The difference in distance walked before and after intervention in the combined training group was of $+39.7 \pm 61.4$ m, and the difference in the resistance training group was of -19.2 ± 53.9 m, $p = 0.02$. The study concluded that combination of aerobic and resistance training was more effective than resistance training alone to improve functional performance among haemodialysis patients (**Orcy RB, 2012**).

2.3 Literature related to intradialytic stretching exercises on muscle cramps

A pre experimental study to assess the effect of intradialytic stretching exercises on muscle cramps among patients undergoing haemodialysis was conducted in selected hospitals at Chennai. Forty five patients undergoing haemodialysis who experienced muscle cramps were included purposively. Intradialytic exercises were performed every 30 minutes during the last two hours of dialysis. It was found that in the pretest 53.3% had severe muscle cramps, 46.7% had moderate muscle cramps. After performing the exercises 40% had no cramps, 24.4% had mild and 35.6% had moderate cramps. The study concluded that intradialytic stretching exercises during the last two hours of haemodialysis helps to reduce and prevent the muscle cramps. **(Basemath.S.S. Morris, 2014).**

A randomized controlled trial was done in Hanze University, Groningen to assess the stretching before sleep reduces the frequency and severity of nocturnal leg cramps in older adults. Eighty adults over 55 years with nocturnal leg cramps who were not being treated with quinine were selected. Pretest posttest with comparison group design was adopted. Participants recorded the frequency of nocturnal leg cramps. At six weeks, the frequency of nocturnal leg cramps decreased significantly more in the experimental group with the mean difference of 1.2 cramps per night (95% CI 0.6 to 1.8). The severity of the nocturnal leg cramps had also decreased significantly more in the experimental group than in the control group with the mean difference 1.3 cm (95% CI 0.9 to 1.7) on the 10-cm visual analogue scale. The study concluded that stretching before going to sleep reduces the frequency and severity of nocturnal leg cramps in older adults **(Hallegraeff.J.M, et al., 2013).**

A study to assess the physical therapy during haemodialysis in patients with chronic kidney disease was conducted .The therapy consists of muscle strengthening exercises, stretching and stationary exercises. Fifty six chronic kidney disease patients were participated. They underwent evaluation before the start of the program and after the training. The mean values of HR, RR, BP at the end of the test were 97.57 ± 16.82 beats per minute 22.26 ± 2.46 breaths per minute and 133.43 ± 15.52 mmHg. The Borg

Scale scores had a mean initial value of 0.97 ± 0.98 and a median of 0.50. After performing the exercises the mean value was 0.43 ± 0.47 and median value equal to the initial, 0.50 ($p < 0.001$). Thus there was a significant difference between these scores and concluded that there is an improvement in the quality of life and physical ability of patients with chronic kidney disease **(Silva. S.F, et al., 2013)**.

A study was conducted in Michigan, U.S.A to prevent the haemodialysis related muscle cramps cramps by intradialytic use of sequential compression devices. Four patients on thrice-weekly haemodialysis who experienced two or more episodes of lower extremity cramps weekly in the month before the study were selected. Sequential compression devices were applied before each haemodialysis on both the legs and compressions were intermittently applied at 40 mmHg during treatment. All four patients were reported the complete resolution of cramping during the study period that lasted 1 month or 12 consecutive dialysis treatments. The study concluded that application of sequential compression devices to lower extremity may prevent the generation of lower extremity haemodialysis -related cramping in a selected group of patients **(Ahsan M, et al., 2010)**.

A prospective, randomized single-blinded controlled trial was done in Sriraj hospital, Mahidol University, Thailand to assess the effect of calf stretching box on stretching calf muscle compliance. Eighty patients older than 45 years with calf muscles tightness were enrolled. Patients were randomized into two groups, the study group (stretching by using calf stretching box) and the control group (stretching by the conventional exercise method). Patients in both groups were asked to hold the stretch for at least 1 minute and to perform the stretching program at least two times per day, every day for two weeks. They were asked to record the real frequency and duration of their exercise and complications in a logbook every day. It was found that there was a reduction in the calf muscle tightness with less pain than the control group ($p < 0.05$). The study concluded that the stretching calf muscle with calf stretching box can increase compliance, decrease calf muscle tightness and decrease complications when compared with the conventional exercise method. **(Chadchavalpanichaya, Srisawasdi, Suwannakin, 2009)**.

A quasi experimental study to assess the impact of stretching exercises protocol on reduction of muscle cramps during haemodialysis among chronic renal failure patients was conducted in kidney dialysis department of Assuit University hospitals. Among 60 patients the calf stretching exercises were taught for a duration of 5minutes per hour. It was found that there was a lack of knowledge and skills related to muscle cramps before nursing instruction protocol. But there was a statistical significant difference after performance of exercises as 8.3% and 55.0% respectively at $p < 0.001$ and concluded that there is a need of effective education programme to help the patient with muscle cramps. **(Magda Mohamed, Amal Mohamed, Shalabia Abo Zead, 2007).**

CHAPTER III

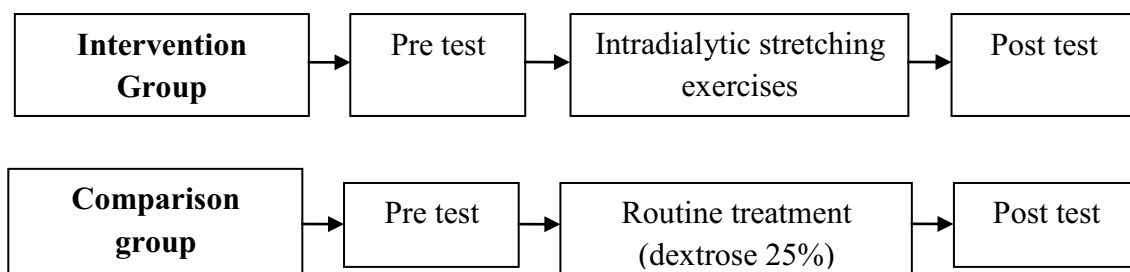
MATERIALS AND METHODS

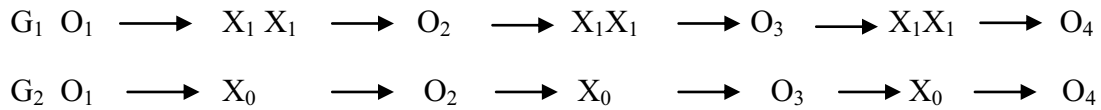
Research design of a study spells out the basic strategies that researchers adopt to develop evidence that is accurate and interpretable (Polit, 2009). The present study is designed to find out the effectiveness of intradialytic stretching exercises on prevention and reduction of muscle cramps among patients undergoing haemodialysis. The study was conducted by adopting the steps of research process such as research design, setting, selection of population and sampling, criteria for selecting the samples, instruments and tool for data collection and method of data analysis. Pilot study was conducted and changes were incorporated.

3.1 Research approach: This study adopted quasi experimental research approach. According to Cook and Campbell quasi experimental designs facilitates the search for knowledge and examination of causality in situations in which complete control is not possible (Burns N., 2009).

Research design:

Quasi Experimental Design Pre-Test Post-Test With Control Group: Quasi experiments are like true experiments that involve an intervention. This design lack randomization, the signature of a true experiment. The signature of a quasi experimental design is an intervention in the absence of randomization. The pre-test post-test designs are widely used in behavioral research primarily for the purpose of comparing the groups resulting from the experimental treatment (Polit, 2009).





G₁- Intervention group

G₂- Comparison group

X₁- Performing intradialytic stretching exercises during the 3rd and 4th hour of dialysis for every 30 minutes, twice per sitting.

X₀- Administration of dextrose 25% during the intradialytic period.

O₁- Pre test assessment of muscle cramps using the cramp questionnaire chart and visual analogue scale.

O₂- Post test I (Assessment of muscle cramps)

O₃- Post test II (Assessment of muscle cramps)

O₄- Post test III (Assessment of muscle cramps)

3.2 Variables of the study:

Independent Variable: The independent variable of this study is intradialytic stretching exercises and dextrose 25%.

Dependent Variable: The dependent variable of this study is prevention and reduction of muscle cramps

3.3 Setting of the study: This study was conducted in dialysis unit of PSG hospitals, peelamedu Coimbatore. The hospital is a multispeciality hospital and research centre with bed strength of 1315. The hospital is certified by national accredited board for hospitals and health care provider (NABH). The dialysis department of this hospital which has bed strength of 25. The total number of patients undergoing haemodialysis for each month is 160 and each day they have four shifts with the population of 70 patients. The dialysis department of this hospital has 1 in-charge dialysis technician, 20 experienced and qualified staff nurses, 4 technicians, ward clerk and ward assistants. The staff nurses of this hospital undergo training and classes to upgrade their knowledge through ward teaching programme.

3.4 Population and Sampling:

The sampling technique used in this study was purposive sampling. Sample size was calculated considering the total number of patients undergoing haemodialysis in the past one year (2014). The sample size was decided to be 60 patients with muscle cramps. The patients with muscle cramps who met the inclusion and exclusion criteria were selected for this study. Consent for participation was obtained verbally and also in written from the patients.

3.4.1 Sampling technique and sample size: All patients who met the inclusion criteria were selected using the purposive sampling technique. Total samples were 60 patients. In each group 30 samples were assigned (Intervention group=30 and Comparison group=30)

Precision Method:

$$n = \frac{Z^2 SD^2}{(1 \% \text{ of mean})^2}$$

Z= value of normal deviate at P<0.05 level of significance.

SD= standard deviation of total population.

Total population mean=187

$$Z = 1.96$$

Standard deviation = 5.12

$$n = \frac{(1.96)^2 (5.12)^2}{(1.87)^2}$$

$$n = 29$$

According to precision method the sample size is multiplied by 2

Therefore n = 58

Hence the estimated sample size was 58 samples. In this study 60 samples were selected according to the inclusion criteria.

3.4.2 Sample selection criteria:

Inclusion Criteria:

- Patients who had muscle cramps during haemodialysis.
- Patients who are alert and cooperative.

Exclusion Criteria:

- Patients undergoing emergency and first haemodialysis
- Patients with femoral catheter
- Patients with any lower limb disability

3.5 Instruments and tool for data collection:

SECTION A

PART A: Demographic data: It includes age, gender, diagnosis, duration of illness, number of haemodialysis, education and occupation of the patient. (Annexure IV)

PART B: Clinical variable: It includes duration of haemodialysis treatment, sittings per week, period of experiencing cramps, location of muscle cramps, muscles involved in cramps, associated medical illness and quality of life. (Annexure IV)

SECTION B: Cramp questionnaire chart and visual analogue scale. (Annexure IV)

The cramp questionnaire chart was developed by Basemath.S.S.Morris.

The cramp questionnaire chart was designed to assess the level of muscle cramps during hemodialysis, before and after intervention. It contains various features of muscle cramps such as the frequency of muscle cramps, duration of muscle cramps, level of pain, temperature and discomfort which was comprehensively scored as level of muscle cramps ranging from (0-13).

Score Interpretation:

0	No cramps
1-4	Mild cramps
5-8	Moderate cramps
9-13	Severe cramps

3.5.1 Validity and reliability of the study:

The tool was designed by Ms.Basemath S.S Morris, Assistant Professor, Jennys College of Nursing, Trichy. The tool was developed on the basis of extensive review of literature, discussion with experts in the field of nursing and the investigator's professional experience. Interrater observational method was used to test the reliability of the tool. The reliability of the tool was interpreted using the 'Karl Pearson correlation' method. It has established a reliability value of 'r' 0.93. It showed the internal consistency of the tool. The reliability score of visual analogue scale was found as 'r' 0.97. Validity of the instrument was assessed by obtaining opinion from the experts. Validity and reliability have been tested through pilot study. The obtained reliability value during the pilot study was 0.83.

3.5.2 Techniques of data collection:

Data collection was done for a period of 42 days from 29/06/2015 to 08/08/2015. Pretest was done using the questionnaire and the data was collected through interview method from the patients. The muscle cramps was assessed using the cramp questionnaire chart and visual analogue scale.

Steps of Intervention:

Intradialytic stretching exercises comprises of

- Ankle dorsiflexion
 - Gastrocnemius stretching
 - Soleus stretching
 - Hamstring stretching
 - Quadriceps stretching
- Patients from intervention group were administered intradialytic stretching exercises during the third and fourth hour of haemodialysis.
 - Each session of this exercises program was for 15 minutes.
 - Exercises administered two times per sitting.
 - Exercises administered until the patients complete the post test III.

- After intervention post assessment of muscle cramps was done during the fourth, seventh, and tenth sitting of haemodialysis.
- Patients from the comparison group were administered dextrose 25% during the intradialytic period.
- Post assessment of muscle cramps was done during the haemodialysis.

3.5.3 Data collection procedure:

After getting the ethical clearance from the institutional human ethics committee of PSG institution. A formal permission letter was obtained from the medical director of PSG hospitals to conduct the study. Samples were selected based upon the inclusion and the exclusion criteria. Informed consent was obtained from the selected samples to do the study. For the intervention group the pretest was done on the first sitting of haemodialysis. Intradialytic stretching exercises were given during the second and third sitting of haemodialysis. The post test was done on the fourth, seventh, tenth sitting of haemodialysis. For the comparison group the pretest was done on the first sitting of haemodialysis. Dextrose 25% were administered to the patient during the intradialytic period and the post test was done during haemodialysis.

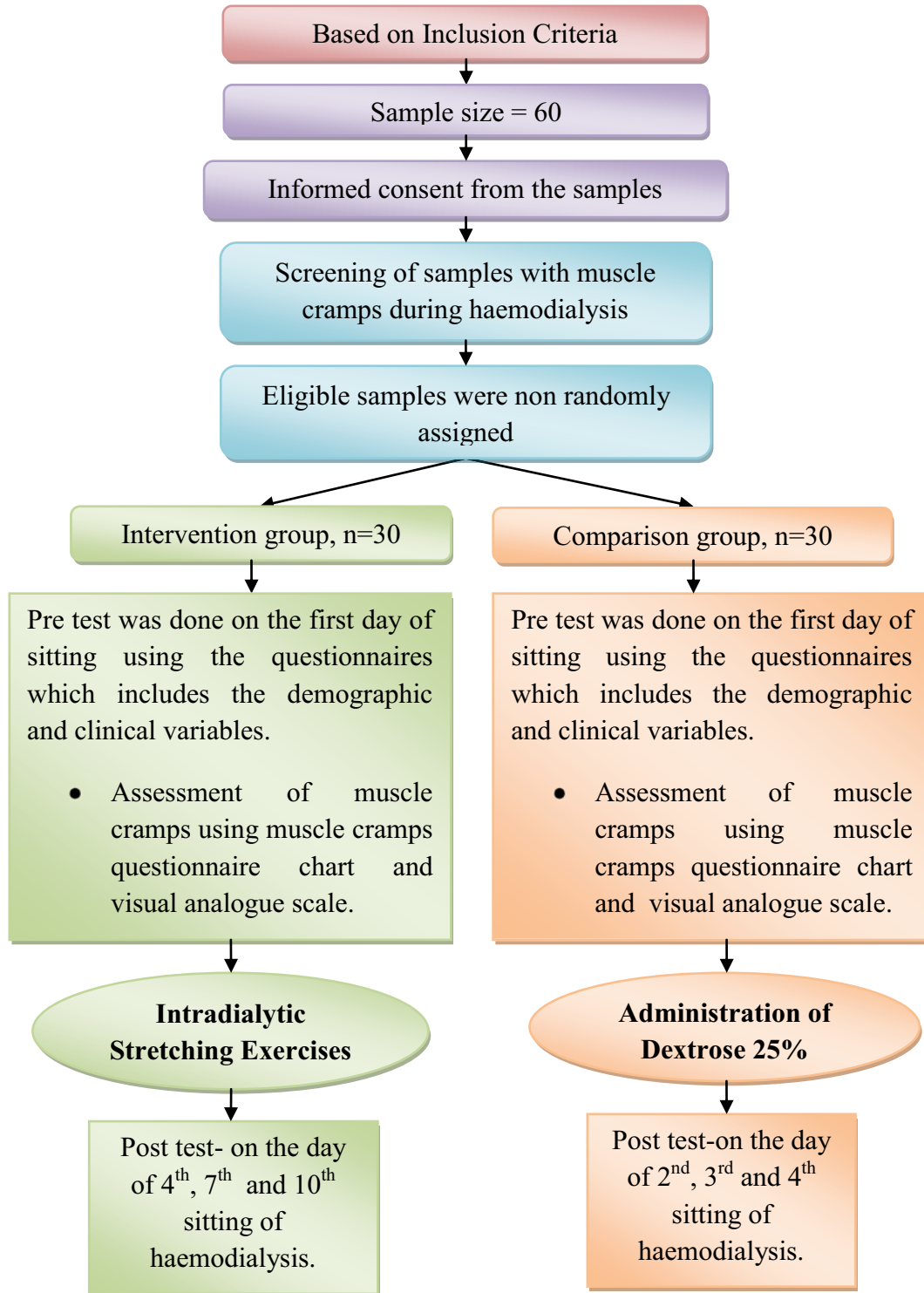


Figure 3.1 Data collection procedure

3.6 Ethical approval:

The institutional human ethics committee (IHEC), PSG institute of medical science and research had reviewed the proposal on January 2015 in its full board meeting and approved the study to conduct. After getting the clearance from the institutional human ethics committee (IHEC), pilot study was done after the findings of pilot study, main study data collection was done. (Annexure II)

3.7 Report of the pilot study:

Pilot study was conducted to test the practicability and feasibility of the tool. It was conducted for a period of one week from 25 -5-15 to 30-5-15 in dialysis unit, PSG hospitals. For pilot study 14 patients were selected according to the inclusion criteria. Among 14 patients 7 patients in intervention group and 7 patients in comparison group were randomly assigned. After performing intradialytic stretching exercises to the intervention group feature of muscle cramps were assessed using muscle cramps questionnaire chart and visual analogue scale. In comparison group feature of muscle cramps were assessed without intervention .The data were tabulated and analyzed using descriptive and inferential statistics. By using paired 't' test data analysis was done and the 't' test value is 3.91 which is significant at the level of $p=2.45$.The finding of the study reveals that there is a significant difference in the level of muscle cramps and the intradialytic stretching exercises between intervention and comparison group of patients undergoing haemodialysis.

3.7.1 Changes brought after pilot study:

There were no changes brought after pilot study.

3.8 Data analysis plan:

Both descriptive and inferential statistics will be used to analyze the data.

Paired 't' test : This test will be used to find the significant differences between the pre-test and post-test level of muscle cramps among patients in both the groups.

Independent 't' test : This test will be used to assess the significant difference in post-test level of muscle cramps between the intervention and comparison group.

CHAPTER-IV

DATA ANALYSIS AND INTERPRETATION

Analysis is a process of organizing the data in such a way that research question can be answered (Polit and Hungler, 1999). This chapter deals with the analysis of the data collected from the patient and the interpretation of the results helps in making sense of the results of a study. The data was collected to assess the effectiveness of the intradialytic stretching exercises in preventing or reducing the muscle cramps during haemodialysis.

The analysis in this chapter includes:

SECTIONS:

1. Frequency and percentage distribution of patients according to demographic profile and clinical condition.
2. Assessment of the pre-test and post-test scores of muscle cramps during haemodialysis among intervention and comparison group using the cramp questionnaire chart and visual analogue scale.
3. Comparison between pre test and post test scores of muscle cramps among patients in intervention and comparison group using student 't' test.
4. Effectiveness of intradialytic stretching exercises and routine treatment in preventing and reducing the muscle cramps between intervention and comparison group among patients undergoing haemodialysis using independent 't' test.
5. Association between the level of muscle cramps and selected demographic variables among intervention and comparison group of patients undergoing haemodialysis using chi square test.

SECTION I

TABLE 4.1: Frequency and percentage distribution of demographic profile of patients undergoing haemodialysis

n=60

Baseline data	Intervention group n=30				Comparison group n=30			
Age and gender (Age in years)	Male	%	Female	%	Male	%	Female	%
35-44	0	0	2	6.6	4	13.3	2	6.6
45-54	5	16.6	8	26.6	6	20	7	23.3
55-64	6	20	4	13.3	4	13.3	0	0
65-74	4	13.3	1	3.3	4	13.3	3	10
Duration of chronic kidney disease (years)								
0-1	11		36.6		5		16.6	
2-3	8		26.6		11		36.6	
>3	11		36.6		14		46.6	
Number of haemodialysis								
<100	11		36.6		3		10	
101-200	2		6.6		1		3.3	
201-300	4		13.3		6		20	
301-400	1		3.3		3		10	
>400	12		40		17		56.6	
Education								
Illiterate	10		33.3		19		63.3	
High school	16		53.3		2		6.6	
Higher secondary	1		3.3		1		3.3	
Graduate	3		10		6		20	
Post graduate	0		0		2		6.6	
Occupation								
Unskilled Worker	3		10		0		0	
Professional	1		6.6		3		10	
House Wife	15		50		6		20	
Unemployed	11		36.6		21		70	

The table 4.1 reveals that nearly half of the patients belongs to 45-54 years of age which comprises of 13(43.3%) patients from the intervention group and 13(43.3%) patients from the comparison group. Majority of the patients were male which comprises of 15(50%) patients from the intervention group and 18 (60%) patients from the comparison group. Most of the patients were diagnosed to have chronic kidney disease for more than 3 years which comprises of 11(36.6%) patients from the intervention group and 14(46.6%) patients from the comparison group. Fifty percentage of the patients were undergone 400 times of haemodialysis which consists of 12(40%) patients from the intervention group and 17(56.6%) patients from the comparison group. Half of the patients were illiterate which comprises of 10(33.3%) patients from the intervention group and 19(63.3%) patients from the comparison group. Most of the patients were unemployed which comprises of 11(36.6%) patients from the intervention group and 21(70%) patients from the comparison group.

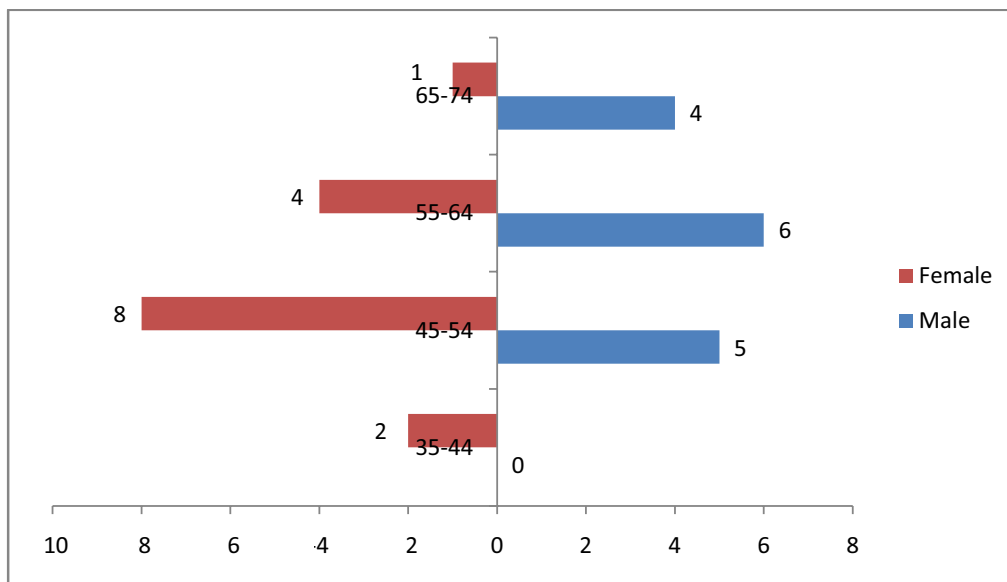


Figure 4.1: Frequency distribution of Age and Gender in intervention group

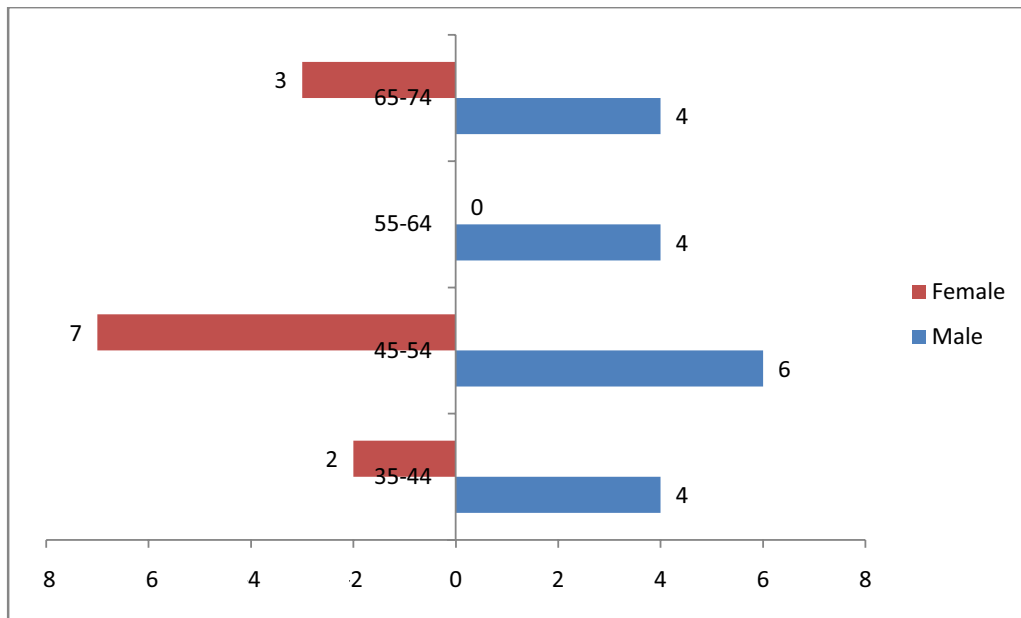


Figure 4.2: Frequency distribution of Age and Gender in comparison group

TABLE 4.2: Frequency and percentage distribution of clinical variables of patients undergoing haemodialysis

n=60				
Clinical Variables	Intervention group n=30		Comparison group n=30	
	f	%	f	%
Duration of haemodialysis treatment (years)				
1-2	0	0	0	0
3-4	9	30	3	10
>4	21	70	27	90
Hours during haemodialysis				
4 hours	30	100	30	100
6 hours	0	0	0	0
Sittings per week				
Twice	18	60	13	43.3
Thrice	12	40	17	56.6
Cramps occurred during haemodialysis				
Middle hour	5	16.6	15	50
Last hour	25	83.3	15	50
Muscle cramps restrict the activities and movements				
Yes	30	100	30	100
Location of muscle cramps				
Right leg	3	10	5	16.6
Left leg	13	43.3	12	40
Both legs	14	46.6	13	43.3
Muscles involved in cramps				
Calf	15	50	21	70
Hamstring	9	30	2	6.6
Soleus	6	20	7	23.3
Associated medical illness				
Diabetes mellitus	10	33.3	10	33.3
No associated medical illness	20	66.6	20	66.6
Quality of life deteriorated				
Very much	14	46.6	10	33.3
Somewhat	16	53.3	20	66.6
Not at all	0	0	0	0

The table 4.2 describes ninety percentage of the patients were undergone haemodialysis treatment for more than 4 years. All the patients had 4 hours of haemodialysis and experienced muscle cramps which restrict the activities of daily living. Most of the patients were undergone haemodialysis twice in a week .Majority of the patients were experienced muscle cramps during the last hour of haemodialysis which comprises of 25(83.3%)patients from the intervention group and 15(50%) patients from the comparison group. Nearly half of the patients experienced muscle cramps in both the legs which comprises of 14(46.6%) patients from the intervention group and 13 (43.3%) patients from the comparison group. More than half of the patients experienced muscle cramps in calf muscles which includes 15 (50%) patients from the intervention group and 21(70%) patients from the comparison group. Only thirty percentages of patients had associated medical illness.

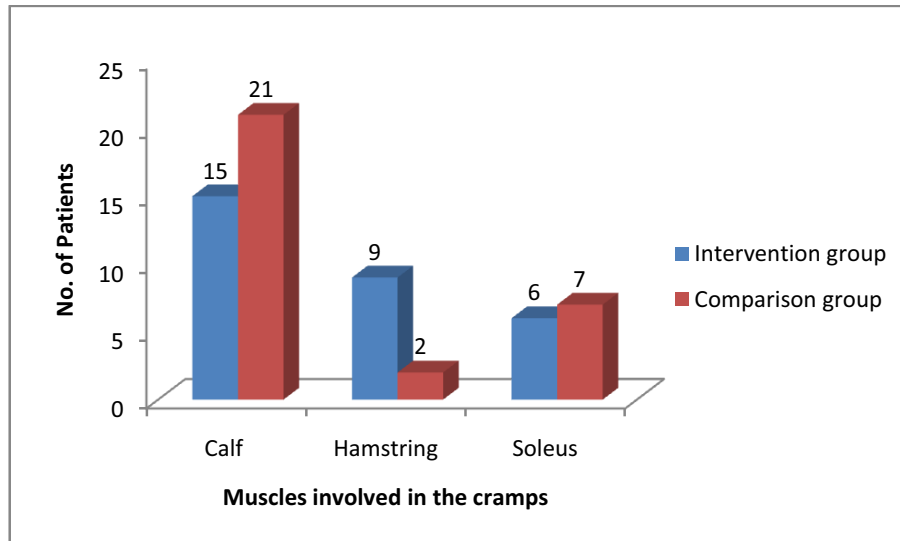


Figure 4.3: Frequency distribution of muscles involved in cramps among intervention and comparison group

SECTION II

Table 4.3: Frequency and percentage distribution of muscle cramps during haemodialysis between pretest and post test I among intervention group

n=30

Sl. no	Feature of muscle cramps	Pre test		Post test I	
		Frequency	%	Frequency	%
1	No cramps (0)	0	0	9	30
2	Mild (1-4)	1	3.3	7	23.3
3	Moderate (5-8)	2	6.6	3	10
4	Severe (9-13)	27	90	11	36.6

The table 4.3 reveals that out of the 30 patients from the intervention group 27 (90%) patients experienced severe muscle cramps. Only 2(6.6%) patients experienced moderate cramps and 1(3.3%) patient experienced mild cramps before intradialytic stretching exercises. During the first post test (ie after performing the intradialytic stretching exercises) 11 (36.6%) patients experienced severe muscle cramps. Only 3 (10%) patients experienced moderate cramps and 7 (23.3%) patients experienced mild cramps. Only 9 (30%) patients did not experience muscle cramps.

Table 4.4: Frequency and percentage distribution of muscle cramps during haemodialysis between pretest and post test II among intervention group

n=30

Sl. no	Feature of muscle cramps	Pre test		Post test II	
		Frequency	%	Frequency	%
1	No cramps (0)	0	0	19	63.3
2	Mild (1-4)	1	3.3	8	26.6
3	Moderate (5-8)	2	6.6	1	3.3
4	Severe (9-13)	27	90	2	6.6

As shown in table 4.4 most of the patients 19(63.3%) did not experience cramps after performing intradialytic stretching exercises. Only 2(6.6%) of the patients experienced severe cramps.

Table 4.5: Frequency and percentage distribution of muscle cramps during haemodialysis between pretest and post test III among intervention group

n=30

Sl. no	Feature of muscle cramps	Pre test		Post test III	
		Frequency	%	Frequency	%
1	No cramps (0)	0	0	20	66.6
2	Mild (1-4)	1	3.3	7	23.3
3	Moderate (5-8)	2	6.6	0	0
4	Severe (9-13)	27	90	3	10

The table 4.5 reveals that during the third post test more than half of the patients 20 (66.6%) did not experience muscle cramps after the intervention. Only 3 (10%) patients experienced severe muscle cramps. None of the patients experienced moderate muscle cramps. The result describes the effect of intradialytic stretching exercises in reducing the muscle cramps during haemodialysis.

Table 4.6: Frequency and percentage distribution of muscle cramps during haemodialysis between pretest and post test I among comparison group

n=30

Sl. No	Feature of muscle cramps	Pre test		Post test I	
		Frequency	%	Frequency	%
1	No cramps (0)	0	0	12	40
2	Mild (1-4)	0	0	3	10
3	Moderate (5-8)	1	3.3	0	0
4	Severe (9-13)	29	96.6	15	50

As shown in table 4.6 reveals that out of the 30 patients from the comparison group most of the patients 29(96.6%) patients experienced severe muscle cramps. only 1(3.3%) patient experienced moderate cramps. During the first post test (ie administration of dextrose 25%) half of the patients 15 (50 %) experienced severe muscle cramps. Only 3(10%) patients experienced mild cramps and 12(40 %) patients did not experience cramps.

Table 4.7: Frequency and percentage distribution of muscle cramps during hemodialysis between pretest and post test II among comparison group

n=30

Sl. No	Feature of muscle cramps	Pre test		Post test II	
		Frequency	%	Frequency	%
1	No cramps (0)	0	0	15	50
2	Mild (1-4)	0	0	3	10
3	Moderate (5-8)	1	3.3	3	10
4	Severe (9-13)	29	96.6	9	30

The table 4.7 describes out of the 30 patients from the control group half of the patients 15 (50%) did not experience muscle cramps. Only 3(10%) patients experienced mild and moderate cramps. The result describes the effect of dextrose 25% in reducing the muscle cramps during haemodialysis.

Table 4.8: Frequency and percentage distribution of muscle cramps during haemodialysis between pretest and post test III among comparison group

n=30

Sl. No	Feature of muscle cramps	Pre test		Post test III	
		Frequency	%	Frequency	%
1	No cramps (0)	0	0	1	3.3
2	Mild (1-4)	0	0	1	3.3
3	Moderate (5-8)	1	3.3	2	6.6
4	Severe (9-13)	29	96.6	26	86.6

Table 4.8 reveals that most of the patients 26 (86.6%) patients experienced severe muscle cramps. Only 1(3.3%) patient did not experience cramps. The results describes that there is no effect in the reduction of muscle cramps during haemodialysis with the routine treatment.

Table 4.9

Comparison of muscle cramps among intervention group and the comparison group based on the muscle cramps score

n=60

Sl. No	Muscle cramps	Interpretation	Intervention group n=30						Comparison group n=30					
			Before			After			Before			After		
			Pre test		Post test 1		Post test 2		Post test 3		Pre test		Post test 1	
			f	%	f	%	f	%	f	%	f	%	f	%
1	0	No cramps	0	0	9	30	19	63.3	20	66.6	0	0	12	40
2	1-4	Mild cramps	1	3.3	7	23.3	8	26.6	7	23.3	0	0	3	10
3	5-8	Moderate cramps	2	6.6	3	10	1	3.3	0	0	1	3.3	0	0
4	9-13	Severe cramps	27	90	11	36.6	2	6.6	3	10	29	96.6	15	50
													9	30
													26	86.6

Table: 4.10: Frequency distribution of pain level of muscle cramps among intervention group and the comparison group based on visual analogue scale score

n=60

Sl. No	Level of pain	Interpretation	Intervention group n=30						Comparison group n=30					
			Before			After			Before			After		
			Pre test			Post test 1			Pre test			Post test 1		
			f	%		f	%		f	%		f	%	
1	0	No pain	0	0		8	26.6	20	66.6	21	70	0	0	
2	1-3	Mild pain	1	3.3		8	26.6	7	23.3	0	0	3	10	
3	4-6	Moderate pain	8	26.6		4	13.3	2	6.6	3	10	2	6.6	
4	7-10	Severe pain	21	70		10	33.3	1	3.3	6	20	13	43.3	
												7	23.3	
												5	16.6	
												3	10	
												15	50	
												0	0	
												1	3.3	
												6	20	
												23	76.6	

Among intervention group during the pretest 21(70%) of patients experienced severe cramps. After performing the intradialytic stretching exercises the post test I score shows that 10 (33.3%) patients experienced severe pain. The post test II score describes more than half of the patients 20(66.6%) did not experience pain and the post test III score describes majority of the patients 21(70%) did not experience pain.

In comparison group during the pretest 28(93.3%) of patients experienced severe pain. After administration of dextrose 25%the post test I score shows nearly half of the patients 13(43.3%) experienced severe pain. The post test II score describes half of the patients 15(50%) did not experience pain and the post test III score shows that majority of the patients 23(76.6%) experienced severe pain.

Table 4.11: Frequency and percentage distribution of frequency of muscle cramps among intervention group and the comparison group

n=60

Sl. No	Feature of Muscle cramps	Intervention group						Comparison group					
		Before			After			Before			After		
		Pre test		Post test 1		Post test 2		Pre test		Post test 1		Post test 2	
		f	%	f	%	f	%	f	%	f	%	f	%
1	Does not occur	0	0	8	26.6	18	60	0	0	12	40	15	50
2	Cramps occur less than 3 times/ hour	12	40	16	53.3	11	36.6	4	13.3	4	13.3	4	13.3
3	Cramps occur more than 3 times/ hour	18	60	6	20	1	3.3	26	86.6	14	46.6	11	36.6
												26	86.6

Among intervention group during the pretest 18(60%) of patients experienced cramps more than 3 times per hour. After performing the intradialytic stretching exercises the post test I score shows that majority of the patients 16(53.3%) experienced cramps less than 3 times per hour. The post test II score describes majority of the patients 18(60%) did not experience cramps and the post test III score shows more than half of the patients 20(66.6%) did not experience cramps.

In comparison group during the pretest 26(86.6%) of patients experienced cramps more than 3 times per hour. After administration of dextrose 25%the post test I score shows nearly half of the patients 14(46.6%) experienced cramps more than 3 times per hour. The post test II score describes half of the patients 15(50%) did not experience cramps and the post test III score shows that majority of the patients 26(86.6%) experienced cramps more than 3 times per hour.

Table 4.12: Frequency and percentage distribution of duration of muscle cramps among intervention group and the comparison group

n=60

Sl. No	Feature of Muscle cramps	Intervention group						Comparison group					
		Before			After			Before			After		
		Pre test		Post test 1		Post test 2		Post test 3		Pre test		Post test 1	
		f	%	f	%	f	%	f	%	f	%	f	%
1	Does not occur	0	0	8	26.6	19	63.3	20	66.6	0	0	12	40
2	Cramps lasts for less than 5 minutes	3	10	8	26.6	8	26.6	7	23.3	0	0	3	10
3	Cramps last for more than 5 minutes	27	90	14	46.6	3	10	3	10	30	100	15	50
												10	33.3
												27	90

Among intervention group during the pretest 27(90%) of patients experienced cramps more than 5 minutes. After performing the intradialytic stretching exercises the post test I score shows that nearly half of the patients 14(46.6%) experienced cramps more than 5 minutes. The post test II score describes more than half of the patients 19(63.3%) did not experience cramps and the post test III score shows majority of the patients 20(66.6%) did not experience cramps.

In comparison group during the pretest all the patients 30(100%) experienced cramps more than 5 minutes. After administration of dextrose 25% the post test I score shows half of the patients 15(50%) experienced cramps more than 5 minutes. The post test II score describes half of the patients 15(50%) did not experience cramps and the post test III score shows that majority of the patients 27(90%) experienced cramps more than 5 minutes.

Table 4.13: Frequency and percentage distribution of temperature in leg among intervention group and the comparison group

n=60

Sl. No	Feature of Muscle cramps	Intervention group n=30						Comparison group n=30					
		Before			After			Before			After		
		Pre test		Post test 1		Post test 2		Post test 3		Pre test		Post test 1	
		f	%	f	%	f	%	f	%	f	%	f	%
1	Warm	4	13.3	16	53.3	26	86.6	27	90	13	43.3	20	66.6
2	Cold	11	36.6	6	20	3	10	2	6.6	5	16.6	5	16.6
3	Cold/Clammy	15	50	8	26.6	1	3.3	1	3.3	12	40	3	10
												14	46.6

Among intervention group during the pretest half of the patients 15(50%) experienced cold and clammy temperature. After performing the intradialytic stretching exercises the post test I score shows that more than half of the patients 16(53.3%) experienced warm temperature. The post test II score describes majority of the patients 26(86.6%) experienced warm temperature and the post test III score shows majority of the patients 27(90%) experienced warm temperature.

In comparison group during the pretest most of the patients 13(43.3%) experienced warm temperature. After administration of dextrose 25%the post test I score shows only 5(16.6%) of the experienced cold and clammy temperature. The post test II score describes more than half of the patients 20(66.6%) experienced warm temperature and the post test III score shows nearly half of the patients 14(46.6%) experienced cold and clammy temperature.

Table 4.14: Frequency and percentage distribution of discomfort among the intervention group and the comparison group

n=60

Sl. No	Feature of Muscle cramps	Intervention group n=30						Comparison group n=30					
		Before			After			Before			After		
		Pre test		Post test 1		Post test 2		Pre test		Post test 1		Post test 2	
		f	%	f	%	f	%	f	%	f	%	f	%
1	No Cramps	0	0	8	26.6	20	66.6	0	0	12	40	15	50
2	Perceptible	1	3.3	7	23.3	7	23.3	0	0	3	10	4	13.3
3	Sensitive	2	6.6	3	10	1	3.3	0	0	5	16.6	2	6.6
4	Painful	13	43.3	6	20	1	3.3	0	0	11	36.6	0	0
5	Unbearable	14	46.6	6	20	1	3.3	2	6.6	10	33.3	6	20
												15	50

Among intervention group during the pretest nearly half of the patients 14(46.6%) experienced unbearable muscle cramps. After performing the intradialytic stretching exercises the post test I score shows that only 6(20%) experienced unbearable cramps. The post test II score describes majority of the patients 20(66.6%) did not experience cramps and the post test III score shows that only 2(6.6%) experienced unbearable muscle cramps.

In comparison group during the pretest most of the patients 19(63.3%) experienced unbearable cramps. After administration of dextrose 25%the post test I score shows most of the patients 10 (33.3%) experienced unbearable cramps. The post test II score describes half of the patients 15(50%) did not experience cramps and the post test III score shows half of the patients 15(50%) experienced unbearable muscle cramps.

SECTION III

Table 4.15: Comparison of pretest and post test I level of muscle cramps among patients undergoing haemodialysis in intervention group using paired 't' test

n=30

Sl. No	Intervention group	Mean	SD	Calculated 't' value	Table value
1	Pretest	10.86	1.95	6.08*	2.04
2	Posttest I	5.93	4.98		

Statistically Significant-* $p < 0.05$

The observed value is 6.08 which is greater than the table value (2.04) at $p=0.05$ level of significance. This indicates that there is a significant difference between the pretest and the first post test of muscle cramps score among patients who received intradialytic stretching exercises. This showed that intradialytic stretching exercises has an effect in reducing the muscle cramps.

Table 4.16: Comparison of pretest and post test II level of muscle cramps among patients undergoing haemodialysis in intervention group using paired 't' test

n=30

Sl. No	Intervention group	Mean	SD	Calculated 't' value	Table value
1	Pretest	10.86	1.95	13.75*	2.04
2	Posttest II	4.26	4.80		

Statistically Significant-* $p < 0.05$

The observed value is 13.75 which is greater than the table value (2.04) at $p=0.05$ level of significance. This indicates that there is a significant difference between the pretest and the second post test of muscle cramps score among patients who received intradialytic stretching exercises. This showed that intradialytic stretching exercises has an effect in reducing muscle cramps.

Table 4.17. Comparison of pretest and post test III level of muscle cramps among patients undergoing haemodialysis in intervention group using paired 't' test

n=30

Sl. No	Intervention group	Mean	SD	Calculated 't' value	Table value
1	Pretest	10.86	1.95	12.69*	2.04
2	Posttest III	2.1	3.67		

Statistically Significant-*p<0.05

The observed value is 12.69 which is greater than the table value (2.04) at p=0.05 level of significance. This indicates that there is a significant difference between the pretest and the third post test of muscle cramps score among patients who received intradialytic stretching exercises. This showed that intradialytic stretching exercises has an effect in reducing muscle cramps.

Table 4.18: Comparison of pretest and post test level I of muscle cramps among patients undergoing haemodialysis in comparison group using paired 't' test

n=30

Sl. No	Comparison group	mean	SD	Calculated 't' value	Table value
1	Pretest	11.4	1.35	5.84*	2.04
2	Post test I	6.13	5.61		

Statistically Significant-*p<0.05

The observed value is 5.84 which is greater than the table value (2.04) at p=0.05 level of significance. This indicates that there is a significant difference between the pretest and the first post test of muscle cramps score among patients who received routine treatment. This showed that dextrose 25% has an effect in reducing muscle cramps.

Table 4.19: Comparison of pretest and post test II level of muscle cramps among patients undergoing haemodialysis in comparison group using paired 't' test

n=30

Sl. No	Comparison group	mean	SD	Calculated 't' value	Table value
1	Pretest	11.4	1.35	6.94*	2.04
2	Post test II	4.96	5.21		

Statistically Significant-* $p < 0.05$

The observed value is 6.94 which is greater than the table value (2.04) at $p = 0.05$ level of significance. This indicates that there is a significant difference between the pretest and the second post test of muscle cramps score among patients who received routine treatment. This showed that dextrose 25% has an effect in reducing muscle cramps.

Table 4.20: Comparison of pretest and post test III level of muscle cramps among patients undergoing haemodialysis in comparison group using paired 't' test

n=30

Sl. No	Comparison group	mean	SD	Calculated 't' value	Table value
1	Pretest	11.4	1.35	1.86 ^{NS}	2.04
2	Post test III	10.63	2.85		

NS- Not significant

The observed value is 1.86 which is lesser than the table value (2.04) at $p = 0.05$ level of significance. This indicates that there is no significant difference between the pretest and the third post test score of muscle cramps among patients who has not received the intradialytic stretching exercises. This showed that dextrose 25% has no effect in reducing the muscle cramps.

SECTION IV

Null Hypothesis: There will not be a significant difference in the level of muscle cramps among intervention group receiving intradialytic stretching exercises.

Table 4.21: Comparison of intradialytic stretching exercises and routine treatment in preventing and reducing the muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test I scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Level of muscle cramps		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	5.93	4.98	0.146 ^{NS}	2.02
2.	Comparison group	6.1	5.61		

NS- Not Significant

The table 4.21 describes that the calculated ‘t’ value (0.146) is lesser than the ‘t’ table value (2.02). **So the null hypothesis is accepted** as there is no significant difference in the level of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test I.

Table 4.22: Comparison of intradialytic stretching exercises and routine treatment in preventing and reducing the muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test II scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Level of muscle cramps		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	4.26	4.80	0.541 ^{NS}	2.02
2.	Comparison group	4.96	5.21		

NS- Not Significant

As shown in table 4.22 the calculated ‘t’ value (0.541) is lesser than the ‘t’ table value (2.02). **So the null hypothesis is accepted** as there is no significant difference in the level of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test II.

Table 4.23: Comparison of intradialytic stretching exercises and routine treatment in preventing and reducing the muscle cramps between intervention and comparison group among patients undergoing hemodialysis in both post test III scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Level of muscle cramps		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	2.10	3.67	10.046*	2.02
2.	Comparison group	2.63	2.85		

Statistically Significant -*p<0.05

The table 4.23 reveals that the calculated ‘t’ value (10.046) is greater than the ‘t’ table value (2.02). **So the null hypothesis is rejected** as there is a significant difference in the level of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test III. It implies that the intradialytic stretching exercises helps to reduce the level of muscle cramps.

Table 4.24: Comparison of intradialytic stretching exercises and routine treatment in reducing the pain level of muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test I scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Level of pain		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	1.53	1.22	0 ^{NS}	2.02
2.	Comparison group	1.53	1.39		

NS-Not Significant

The table 4.24 describes that the calculated ‘t’ value (0) is lesser than the ‘t’ table value (2.02). **So the null hypothesis is accepted** as there is no significant difference in the pain level of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test I.

Table 4.25: Comparison of intradialytic stretching exercises and routine treatment in reducing the pain level of muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test II scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Level of pain		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	0.46	0.77	2.68*	2.02
2.	Comparison group	1.13	1.27		

Statistically Significant -*p<0.05

As shown in table 4.25 the calculated ‘t’ value (2.68) is greater than the ‘t’ table value (2.02). **So the null hypothesis is rejected** as there is a significant difference in the pain level of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test II.

Table 4.26: Comparison of intradialytic stretching exercises and routine treatment in reducing the pain level of muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test III scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Level of pain		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	0.7	0.95	6.5*	2.02
2.	Comparison group	2.73	0.51		

Statistically Significant -*p<0.05

The table 4.26 describes that the calculated ‘t’ value (6.5) is greater than the ‘t’ table value (2.02). **So the null hypothesis is rejected** as there is a significant difference in the pain level of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test III.

Table 4.27: Comparison of intradialytic stretching exercises and routine treatment in reducing the frequency of muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test I scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Frequency of muscle cramps		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	0.93	0.70	0.65 ^{NS}	2.02
2.	Comparison group	1.06	0.94		

NS- Not Significant

The table 4.27 describes that the calculated ‘t’ value (0.65) is lesser than the ‘t’ table value (2.02). **So the null hypothesis is accepted** as there is no significant difference in the frequency of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test I.

Table 4.28: Comparison of intradialytic stretching exercises and routine treatment in reducing the frequency of muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test II scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Frequency of muscle cramps		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	0.4	0.56	2.94 [*]	2.02
2.	Comparison group	1.0	0.93		

Statistically Significant - *p<0.05

As shown in table 4.28 the calculated ‘t’ value (2.94) is greater than the ‘t’ table value (2.02). **So the null hypothesis is rejected** as there is a significant difference in the frequency of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test II.

Table 4.29: Comparison of intradialytic stretching exercises and routine treatment in reducing the frequency of muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test III scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Frequency of muscle cramps		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	0.43	0.67	9.28*	2.02
2.	Comparison group	1.8	0.48		

Statistically Significant - *p<0.05

The table 4.29 reveals that the calculated ‘t’ value (9.28) is greater than the ‘t’ table value (2.02). **So the null hypothesis is rejected** as there is a significant difference in the frequency of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test III.

Table 4.30: Comparison of intradialytic stretching exercises and routine treatment in reducing the duration of muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test I scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Duration of muscle cramps		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	1.2	0.84	0.47 ^{NS}	2.02
2.	Comparison group	1.1	0.95		

NS- Not Significant

The table 4.30 describes that the calculated ‘t’ value (0.47) is lesser than the ‘t’ table value (2.02). **So the null hypothesis is accepted** as there is no significant difference in the duration of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test I.

Table 4.31: Comparison of intradialytic stretching exercises and routine treatment in reducing the duration of muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test II scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Duration of muscle cramps		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	0.46	0.68	1.94 ^{NS}	2.02
2.	Comparison group	0.83	0.90		

NS- Not Significant

The table 4.31 shows that the calculated ‘t’ value (1.94) is lesser than the ‘t’ table value (2.02). **So the null hypothesis is accepted** as there is no significant difference in the duration of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test II.

Table 4.32: Comparison of intradialytic stretching exercises and routine treatment in reducing the duration of muscle cramps between intervention and comparison group among patients undergoing haemodialysis in both post test III scores using independent ‘t’ Test

n=60

Sl. No	Study Group	Duration of muscle cramps		‘t’ Test	‘t’ table value
		Mean	SD		
1.	Intervention group	0.36	0.61	12.25*	2.02
2.	Comparison group	1.83	0.45		

Statistically Significant -*p<0.05

As shown in table 4.32 the calculated ‘t’ value (12.25) is greater than the ‘t’ table value (2.02). **So the null hypothesis is rejected** as there is a significant difference in the duration of muscle cramps after intradialytic stretching exercises between intervention group and comparison group in the post test III.

SECTION V

Table 4.33: Association between the level of muscle cramps and selected demographic variables among intervention and comparison group of patients undergoing haemodialysis.

n = 60

Sl. No	Demographic variables	Mild f (%)	Moderate f (%)	Severe f (%)	Degree of freedom	Chi-Square value	Table value	P Value
1	Age in years				6	2.975 NS	12.59	0.8119
	35-44	0(0)	0(0)	8(13.3)				
	45-54	1(1.66)	2(3.33)	23(38.33)				
	55-64	0(0)	1(1.66)	13(21.66)				
	65-74	0(0)	0(0)	12(20)				
2	Gender				2	1.390 NS	5.991	0.4990
	Male	0(0)	2(3.33)	31(51.66)				
	Female	1(1.66)	1(1.66)	25(41.66)				
3	Duration of illness				4	3.522 NS	9.488	0.4745
	0-1	0(0)	0(0)	16(26.66)				
	2-3	1(1.66)	1(1.66)	17(28.33)				
	>3	0(0)	2(3.33)	23(38.33)				
4	Number of haemodialysis				8	7.049 NS	15.50	0.5313
	<100	0(0)	0(0)	14(23.33)				
	101-200	0(0)	0(0)	3(5)				
	201-300	1(1.66)	1(1.66)	8(13.3)				
	301-400	0(0)	0(0)	4(6.66)				
	>400	0	2(3.33)	27(45)				
5	Sittings per week				2	4.224 NS	5.991	0.1209
	Twice	1(1.66)	0(0)	30(50)				
	Thrice	0(0)	3(5)	26(43.33)				
6	Location of muscle cramps				4	9.473 NS	9.488	0.0503
	Right Leg	0(0)	2(3.33)	6(10)				
	Left leg	1(1.66)	0(0)	24(40)				
	Both legs	0(0)	1(1.66)	26(43.33)				
7	Associated medical illness				2	3.509 NS	5.991	0.1729
	Diabetes mellitus	1(1.66)	0(0)	19(31.66)				
	No associated medical illness	0(0)	3(5)	37(61.66)				

NS- Not Significant

Table 4.33 clarifies there was no association between the level of muscle cramps and the selected demographic variables such as age, gender, duration of illness, number of haemodialysis, sittings per week, location of muscle cramps and associated illness.

CHAPTER –V

RESULTS AND DISCUSSION

This chapter deals with the discussion of the study findings and the results by relating with the results of previous studies. The discussion section makes sense of the research results. Muscle cramps during haemodialysis can be so severe that the dialysis treatment can be stopped. Many approaches for the treatment of haemodialysis treatment related cramps have been proposed, but most have been associated with serious side effects. Immediate relief from the cramp can be obtained by passively stretching the affected muscle. The use of regular stretching exercises helps to prevent the muscle cramps (**Memune Sena Ulu, Ahmet Ashen., 2015**).

The present study was conducted to assess the effectiveness of intradialytic stretching exercises on prevention and reduction of muscle cramps among patients undergoing haemodialysis'.

5.1 Demographic profile and clinical variables of patients undergoing haemodialysis:

Most of the patients belongs to 45-54 years of age which comprises of 13 (43.3%) patients from the intervention group and 13(43.3%) patients from the comparison group. This study was supported by a prospective, randomized single-blinded controlled trial in which the mean age of the patients undergoing haemodialysis was older than 45 years (**Chadchavalpanichaya, Srisawasdi, Suwannakin, 2009**).

Majority of the patients were male which comprises of 15(50%) patients from the intervention group and 18(60%) patients from the comparison group. This was stated contradictory by a study in which the majority of the patients were female who has reported muscle cramps. (**Basemath .S.S. Morris, 2014**).

Most of the patients were diagnosed to have chronic kidney disease for more than 3 years which comprises of 11(36.6%) patients from the intervention group and

14(46.6%) patients from the comparison group. It was supported by a study conducted to assess the physical therapy on muscle cramps in which the patients with chronic kidney disease were participated (Silva. S.F, et al., 2013).

More than half of the patients experienced muscle cramps in calf muscles which includes 15(50%) patients from the intervention group and 21(70%) patients from the comparison group. This was supported by a study related to the incidence of muscle cramps in which 83% of the patients are experiencing muscle cramps in the calf muscles (Naylor, Young, 2004).

5.2 Assessment of muscle cramps among patients undergoing haemodialysis after performing intradialytic stretching exercises.

Among 30 patients in intervention group, majority of the patients 11 (36.6%) patients experienced severe muscle cramps during the post test I. More than half of the patients 19 (63.3%) patients did not experience cramps during the post test II. Majority of the patients 20 (66.6%) patients did not experience muscle cramps during the post test III. This results describes the effect of intradialytic stretching exercises in reducing the muscle cramps during haemodialysis. This study were supported by an another study in which performing intradialytic stretching exercises reduces the level of muscle cramps were statistically significant with the level of significance at $p < 0.05$ (Magda Mohamed, Amal Mohamed, Shalabia Abo Zead, 2007).

5.3 Assessment of muscle cramps among patients undergoing haemodialysis after administration of dextrose 25%.

Among 30 patients in comparison group, half of the patients experienced 15 (50 %) patients experienced severe muscle cramps during the post test I. Majority of the patients 15 (50%) did not experience muscle cramps during the post test II. Majority of the patients 26 (86.6%) patients experienced severe muscle cramps during the post test III. The results describes that there is no effect in the reduction of muscle cramps during haemodialysis with the dextrose 25%. This was stated contradictory

by an another study in which administration of 50% of dextrose helps to relieve the dialysis related muscle cramps (Neal. C.R, Resnikoff E, Unger. A.M., 2008).

5.4 Comparison of intradialytic stretching exercises and routine treatment in preventing and reducing the muscle cramps between intervention and comparison group among patients undergoing haemodialysis.

The data shows that there was no significant difference between the intradialytic stretching exercises and the routine treatment during the post test I and II. Only during the post test III there was a significant difference between the intervention at $p < 0.05$ level of significance. Thus the null hypothesis is rejected. The study shows that there is an effectiveness in the prevention and the reduction of muscle cramps during haemodialysis after longer days of therapy. This study concluded that continuous Intradialytic stretching exercises can prevent and reduces the level of muscle cramps during haemodialysis. This was stated a contradictory by a randomized double – blinded cross over study to compare the efficacy of hemodialysis by administration of dextrose (Canzanello. V.J, et al., 2006)

5.5 Assessment of pain level of muscle cramps among patients undergoing haemodialysis after performing intradialytic stretching exercises.

Among 30 patients in intervention group, Most of the patients 10 (33.3%) experienced severe pain during the post test I. Majority of the patients 20 (66.6%) did not experience pain during the post test II. Only 6 (20%) patients experienced severe pain during the post test III. This results describes the effect of intradialytic stretching exercises in reducing the pain level of muscle cramps during haemodialysis. This study were supported by a randomised controlled trial of non drug therapies for lower limb muscle cramps in which performing stretching exercises reduces the level of pain and the severity of the muscle cramps during haemodialysis. (Blyton. F, Chuter. V, Walter. K.E, Burns. J., 2007).

5.6 Assessment of pain level of muscle cramps among patients undergoing haemodialysis after administration of dextrose 25%.

Among 30 patients in comparison group, majority of the patients 13 (43.3%) patients experienced severe pain during the post test I. Half of the patients 15 (50%) did not experience pain during the post test II. Majority of the patients 23 (76.6%) experienced severe pain during the post test III. The results describes that there is no effect in the reduction of level of pain during haemodialysis with the routine treatment. This study was contradicted by a double blind controlled trial in which administration of hypertonic solution helps to reduce the pain level of muscle cramps during haemodialysis. (Richard A. Sherman, et al., 2013).

5.7 Comparison of intradialytic stretching exercises and routine treatment in reducing the pain level of muscle cramps between intervention and comparison group among patients undergoing haemodialysis.

The data shows that there was a significant difference between the intradialytic stretching exercises and the routine treatment in reducing the pain level of muscle cramps at $p < 0.05$ level of significance. This was stated by a contradictory double blinded trial in which administration of hypertonic glucose reduces the muscle cramps and also seems to be a safe treatment. (J. Milutinovich, M.D, et al., 2010)

5.7 Assessment of frequency of muscle cramps among patients undergoing haemodialysis after performing intradialytic stretching exercises.

Among 30 patients in intervention group, more than half of the patients 16(53.3%) experienced cramps less than 3 times per hour during the post test I. Majority of the patients 18(60%) did not experience cramps. Most of the patients 20(66.6%) did not experience cramps during the post test III. This results describes the effect of intradialytic stretching exercises in reducing the frequency of muscle cramps during haemodialysis. This study were supported by a randomized control trial in which stretching before going to sleep reduces the frequency and severity of nocturnal leg cramps in older adults. (Hallegraeff. J.M, et al., 2013).

5.8 Assessment of frequency of muscle cramps among patients undergoing haemodialysis after administration of dextrose 25%.

Among 30 patients in comparison group, nearly half of the patients 14(46.6%) experienced cramps more than 3 times per hour during the post test I. Half of the patients 15(50%) did not experience cramps during the post test II. Majority of the patients 26(86.6%) experienced cramps more than 3 times per hour during the post test III. The results describes that there is no effect in the reduction of frequency of muscle cramps during haemodialysis with the dextrose 25%. This study was supported by a prospective randomized double – blinded cross over study to compare the efficacy of haemodialysis by administration of dextrose (Canzanello. V.J, et al., 2006).

5.9 Comparison of intradialytic stretching exercises and routine treatment in reducing the frequency of muscle cramps between intervention and comparison group among patients undergoing haemodialysis.

The data shows that there was a significant difference between the intradialytic stretching exercises and the routine treatment in reducing the frequency of muscle cramps at $p < 0.05$ level of significance. Thus intradialytic stretching exercises reduces the level of muscle cramps after 6 days of therapy. This study was supported by a factorial randomised controlled trial in which calf stretching exercises helps to prevent the muscle cramps during haemodialysis. (Coppin. R.J, Wicke D.M., 2006)

5.10 Association between the level of muscle cramps and demographic variables in intervention and comparison group among patients undergoing haemodialysis.

There was no association found between the level of muscle cramps and the demographic variables. It was also supported by a study in which the peripheral arterial disease has no relationship on muscle cramps (Brass, Adler, Siestema, et al., 2007).

CHAPTER VI

SUMMARY AND CONCLUSION

The present study focused on preventing and reducing the level of muscle cramps of patients undergoing haemodialysis by providing intradialytic stretching exercises during the third and fourth hour of a haemodialysis.

Literatures related to the intradialytic stretching exercises on reduction of muscle cramps were reviewed. It revealed that intradialytic exercise every 30 minutes during the last two hours of dialysis helped to reduce and even prevent muscle cramps. Some of the other studies revealed that stretching before sleep reduces the nocturnal leg cramps. There were many studies tested the level of muscle cramps by performing resistance exercises than the stretching exercises. Most of the studies were focused on the muscle loss, functional performance, and the efficacy of the haemodialysis. Hence this study was focused on the prevention or reduction of muscle cramps and incorporated this intradialytic stretching exercises as an evidenced based nursing practice.

The design adopted for this study is pre-test post-test with control group, which is a type of quasi-experimental design. The study was conducted on 60 samples those who had muscle cramps during the haemodialysis, during a period of 6 weeks in Dialysis unit PSG hospitals. After obtaining an informed consent, Demographic data was collected by an interview method, level of muscle cramps was assessed using the cramp questionnaire chart (0-13 scores) which is comprehensively scored with the various features of muscle cramps. The intradialytic stretching exercises were given passively to the samples during the third and fourth hour of haemodialysis for a period of 15 minutes twice per sitting. Data were categorized and analyzed using descriptive (mean, percentage, and standard deviation) and inferential statistics (independent 't' test, paired 't' test', chi-square analysis).

6.1 Major findings of the study:

6.1.1 Majority of the patients experienced muscle cramps during the last hour of haemodialysis which comprises of 25(83.3%) patients from the intervention group and 15(50%) patients from the comparison group.

6.1.2 Nearly half of the patients experienced muscle cramps in both the legs which comprises of 14(46.6%) patients from the intervention group and 13(43.3%) patients from the comparison group.

6.1.3 More than half of the patients experienced muscle cramps in calf muscles which includes 15(50%) patients from the intervention group and 21(70%) patients from the comparison group respectively.

6.1.4 Majority of the patients 27(90%) experienced severe muscle cramps during the pre test. After performing the intradialytic stretching exercises most of the patients 20(66.6%) did not experience muscle cramps.

6.1.5 Majority of the patients 26(86.6%) reported severe muscle cramps after administration of dextrose 25%.

6.1.6 It was found statistically that intradialytic stretching exercises reduces the level of muscle cramps during haemodialysis between the groups at ($p < 0.05$).

6.1.7 Comparing the intradialytic stretching exercises and the routine therapy there was a significant difference in the level of muscle cramps during the post test III. The results describes there is an effectiveness in the prevention and the reduction of muscle cramps during haemodialysis after 6 days of therapy. Thus continuous stretching exercises helps to prevent the cramps which was statistically proved.

6.1.8 There was no association between the level of muscle cramps and the demographic variables.

Conclusion:

Muscle cramps are the most prevalent intradialytic complication and it is a subjective feeling that can be expressed by all the patients. There are many pharmacological and non pharmacological measures are adopted to treat the muscle cramps but the data from various studies revealed that there were no complete relief from the cramps. This study was taken up to assess the effectiveness of intradialytic stretching exercises on prevention and the reduction of muscle cramps among patients undergoing haemodialysis at PSG hospitals, Coimbatore. Intradialytic stretching exercises is an effective method which can be used as a preventive therapy in the treatment of muscle cramps. By conclusion intradialytic stretching exercises and the administration of dextrose helps to reduce the level of muscle cramps. But it cannot be prevented by the administration of dextrose. Regular stretching exercises during the haemodialysis prevent the occurrence of muscle cramps and improves the quality of life among the patients undergoing haemodialysis.

6.3 Nursing Implications:

The present study has implications for nursing practice, nursing education, nursing administration and nursing research.

6.3.1 Nursing Practice:

- Intradialytic stretching exercises can be adapted as a procedure to the patients undergoing haemodialysis.
- Nurses can introduce the evidenced based practice of doing this stretching exercises during the haemodialysis session.
- Nurses must emphasize the patients comfort during haemodialysis thus helps to reduce the muscle cramps experienced by the patients.

6.3.2 Nursing Education:

- Intradialytic stretching exercises can be included in the literature on reduction of level of muscle cramps.

- The procedure of performing intradialytic stretching exercises for reducing the level of muscle cramps.
- Nursing students and staff nurses can be taught about the intradialytic stretching exercises for the reduction of muscle cramps.

6.3.3 Nursing Administration:

- Policies for the procedure of intradialytic stretching exercises can be developed based on the study findings by incorporating the stretching exercises in to the procedure.
- Nurse Managers can educate the medical surgical nurses regarding the intradialytic stretching exercises through in service education programs.
- Nursing administrators can take up initiatives in planning and implementation of non- pharmacological therapies along with the routine therapy.

6.3.4 Nursing Research

- Nurse researchers can conduct studies to verify the scientific rationale and the physiology behind the effect of intradialytic stretching exercises on level of muscle cramps.
- Randomized clinical trials could be under taken so that the validity of the results can be increased and it can be incorporated into the evidence based nursing practice.
- Guide lines for the procedure of intradialytic stretching exercises can be prepared.

6.4 Limitations:

This study was limited to the samples of 60

6.5 Recommendations:

6.5.1 Training can be provided to the staff nurses regarding passive intradialytic stretching exercises.

6.5.2 Structured teaching programme on active intradialytic stretching exercises can be provided to the patients undergoing haemodialysis.

6.5.3 Encourage the patients to note the frequency of muscle cramps in a diary after performing the exercises.

6.6 Suggestions for further study:

6.6.1 The study can be repeated by performing massage therapy on reduction of muscle cramps.

6.6.2 A similar study can be conducted by comparing the resistance exercises and the stretching exercises on reduction of muscle cramps.

6.6.3 A similar study can be repeated in another setting in order to increase the external validity.

6.6.4 A study can be done to assess the effect of ultrafiltration rate on the level of muscle cramps.

6.6.6 A cohort study can be done to understand the effect of long term stretching exercises on prevention of muscle cramps.

BIBLIOGRAPHY

1. Abali, C., Adejumo, O. A., Chukwuonye, I., Ogah, S. O., Okwuonu, C. G. (2013). Awareness level of kidney functions and diseases among adults in a Nigerian population. *Journal of American Science*,25(3),158-163.doi:10.4103/0971-4065.139096.
2. Ahsan M. (2004). Prevention of hemodialysis-related muscle cramps by intradialytic use of sequential compression devices. *International Journal of Dialysis*. 8(3),283-286.doi:10.1111/j.1492-7535.2004.01106.
3. Amal Ahmed., Magda Mohamed., Shalabia Abo Zead. (2007) . Impact of stretching exercises protocol on reduction of muscle cramping during haemodialysis, among chronic renal failure patients. *Australian Medical Journal*.5(3),73-76.
4. Amy ,L Clarke et al. (2015). Motivations and barriers to exercise in chronic kidney disease qualitative study. *Journal of Nephrology Dialysis Transplantation Basic And Clinical Renal Science*.30(11),1885-1891.doi:10.1093/ndt/gfv208.
5. Anna Kottgen., Jurgen Floeg., Martin Busch., Stephanie Titze.(2015). Disease burden and risk profile in referred patients with moderate chronic kidney disease. *Journal of Nephrology Dialysis Transplantation*, 30(3), 246-249. doi:10.1093/000355783.
6. Ann Mariner Tomy, Martha Raile Alligood. (2010). Nursing theorists and their work. 7th edition. USA :Mosby Elsevier Publication.
7. Aucella, F., Catizone, L Valente, GL .(2014). The role of physical activity in the CKD setting. *Journal of Nephrology*.37(2-3),97-106.doi:10.1159/000355783.
8. Azra Sadat Musaivan.(2015). Comparing the Effects of Active and Passive Intradialytic Pedaling Exercises on Dialysis Efficacy, Electrolytes, Hemoglobin, Hematocrit, Blood Pressure and Health related quality of life. *Journal of Basic And Clinical Renal Science*.(1),850-854.
9. Bare,G., Cheever,H., Hinkle,L., Smiltzer,C.(2011). Textbook of medical surgical nursing. 12th edition. Delhi: Wolters Kluwer Publication.

10. Bharat ,V Shah., Pavan Malleshappa.(2015).Prevalence of chronic kidney disease and the incidence of acute kidney injury in patients with coronary artery disease in Mumbai, India. *Journal of Gulf Heart Association*.16(2),47-52.doi:10.4103/1995-705.159219.
11. Blyton F., Burns J, Chuter V., Walter KE. (2012). Non-drug therapies for lower limb muscle cramps. *Australian medical journal*.37, 84-96.doi:10.1002/14651858.
12. Brass Adler et al.(2007) . Peripheral arterial disease is not associated with an increased prevalence of intradialytic cramps in patients on maintenance hemodialysis. *American Journal of Nephrology*. 22(5-6),491-496.
13. Brenner .(2009). Exercise performance by hemodialysis patients. *journal of Basic And Clinical Renal Science* 37(4),84-96.doi:10.3810/psm2009.12.1746.
14. Canzanello et al.(2006). Hemodialysis associated muscle cramps. *British Journal of Medicine*.5(4),299-304.doi:10.1111/j1525-139.19921600234.
15. Capitanini.(2014). Dialysis exercise team: The way to sustain exercise programs in hemodialysis patients. *Journal of Kidney And Blood Pressure*.39(2-3),129-133.doi:10.1159/000355787.
16. Chadchavalpanichaya, N et al. (2010). The effect of calf stretching box on stretching calf muscle compliance. *Journal of Medical Association of Thailand*.93(12),1470-1479.
17. Chaugan ,R., Mendonica ,S .(2015). Adequacy of twice weekly haemodialysis in end stage renal disease at a tertiary care dialysis centre. *Indian Journal of Nephrology*.25(6),329-333.doi:10.4103/0971-4065.151762.
18. Cheema ,BS ., Singh, MA, Smith, BC. (2005). A rationale for intradialytic exercise training as standard clinical practice in ESRD. *American Journal of Kidney Diseases*.45(5),912-916.doi:10.1053/j.ajkd2005.01.030.
19. Christoforos, D Giannaki .(2013). Effect of exercise training and dopamine agonists in patients with uremic restless legs syndrome. *British Medical Journal*.14.194-196.doi:10.1186/1471-2369-14-194.

20. Christopher S Wilcox et al. (2008). Therapy in nephrology and hypertension. 3rd edition. Canada: Saunders Elsevier Publication.
21. Colledge,R., Ralston,H., Walker,R.(2006). Principles and practice of medicine. 20th edition. Philadelphia: Churchill Livingstone Elsevier Publication.
22. Coppin et al.(2005).Managing nocturnal leg cramps--calf-stretching exercises and cessation of quinine treatment .*British Journal of General Practice* .55(512),186-191.
23. Dirksen, Heitkemper, Lewis, Brien.(2011). Medical surgical nursing assessment and management of clinical problems .8th edition. USA: Mosby Elsenier Publication.
24. Donald A Molony , Jonathan C Craig. (2009). Evidence- based nephrology. 1st edition. USA: Willey Blackwell Publication.
25. Greek, Marek, Monahan, Neighbors, Sands.(2007). Medical surgical nursing health and illness perspectives. 8th edition. Canada :Mosby Elsevier Publication.
26. Hall AJ.(2008) Cramp and salt balance in ordinary life. *Lancet*.2.231-233.
27. Hallegraff, et al.(2012) An effective stretching regimen to prevent nocturnal leg crmps. *Journal of Physiotherapy*.59(4),279-281.doi:10.1061/S1836-9553.
28. Harrisons et al .(2015). Principles of internal medicine. 19th edition.USA: Mcgraw Hill Education Publishers.
29. Holley, et al. (2012) Muscle cramps in dialysis patients .*CANNT Journal*.25.1235-1237.
30. Jeffrey,S Berns . (2015). Improving care of patients with chronic kidney disease; the 2015 National kidney foundation presidential address. *American Journal of Kidney Diseases*.66.547-551.
31. Jeniffer. R.P. Boore, Kathleen Mccann.(2000) .Fatigue in persons with renal failure who require maintenance haemodialysis. *Journal of Advanced Nursing* 32(5),1132-1142.
32. Jennifer L. Steel., Manisha Jhamb., Mark Unruh.,Steven D Weisbord.(2008). Fatigue in Patients Receiving Maintenance Dialysis: A Review of Definitions,

Measures, and Contributing Factors. *Journal of Kidney Disease*,52(2), 353-365.doi:10.1053/j.askd.2008.05.005.

33. Johansen KL . (2007). Exercise in the end-stage renal disease population. *Journal of American Society of Nephrology*.18(6),1845-1854.

34. Jonathan Himmelfarb, Mohamed H Sayegh. (2010) .Chronic kidney disease, dialysis and transplantation. 3rd edition. Canada :Saunders Elsevier Publication.

35. Joyce M Black. (2009). Medical surgical nursing clinical management for positive outcomes. 8th edition. India: Mosby Elsevier Publication.

36. Julia B George. (2011). Nursing theories the base for professional nursing practice. 6th edition. India: Pearson Publishers.

37. Justine Magnard et al.(2013). Effects of a six – month intradialytic physical activity program and adequate nutritional support on protein energy wasting, physical functioning and quality of life in chronic haemodialysis patients. *British Medical Journal*. 14.259-261.doi:10.1186/1471-2369-14-259.

38. Khajehdehi et al.(2014). Randomized, double-blind, placebo-controlled trial of supplementary vitamins E, C and their combination for treatment of haemodialysis cramps. *Journal of Nephrology Dialysis Transplantation*.16(7),1448-1450.

39. Kirkman.(2014). Anabolic exercise in haemodialysis patients. *Journal of Cachexia Sarcopenia Muscle* .5(3)177–180.doi:10.1007/S13539-014-0140-3.

40. Kirsten, P Koh et al.(2009). Intradialytic versus home based exercise training in haemodialysis patients. *British Medical Journal*. 10.(2),1471-2369.doi:10.1186/1471-2369-10-2.

41. Miller et al.(2005). Vitamin E in hemodialysis associated muscle cramps. *Journal of Muscle And Nerve*. 32(4) ,431-442.

42. Naylor, J.R., Young J.B. (2004).A general population survey of rest cramps. Age Ageing. *Australian Journal of Nephrology*. 23(5),418-420.

43. Neal, C.R. et al. (2008).Treatment of dialysis-related muscle cramps with hypertonic dextrose. *Archives Journal of Internal Medicine*. 14(2),171-173.

44. Nissenson, Fine. (2004). Dialysis therapy. 3rd edition. Philadelphia: Mosby Elsevier Publication.
45. Orcy, R.B et al .(2012). Combined resistance and aerobic exercise better than resistance training alone to improve functional performance of haemodialysis patients. *Journal For Researchers And Clinicians In Physical Therapy*. 17(4),235-343. doi:10.1002/pri.1526.
46. Paul, N Bennet et al. (2013). The effect of an coordinated resistance exercise on physical function among hemodialysis patients. *British Medical Journal of Nephrology*.14.204-206.doi:10.1186/1471-2369-14-204.
47. Polit, D.F.,&Beck, C.T. (2008). Nursing research- Generating and assessing evidence for nursing practice. 8th edition. Philadelphia: Lippincott Publication.
48. Raheleh Mohsensi et al. (2013). The effect of intradialytic aerobic exercise on dialysis efficacy in haemodialysis patients. *Oman Medical Journal*. 28.345-349.
49. Richard A Polin et al. (2012). Nephrology and fluid electrolyte physiology. 2nd edition. USA: Saunders Publications.
50. Richard, A Sherman et al.(2013).Treatment Methods for Kidney Failure: Haemodialysis. *Journal of Basic And Clinical Renal Science*.24(5),1214-1217.
51. Richard, N Hassa., Saleh, M. (2015). Epidemiology and referral patterns of patients with chronic kidney disease in the emirate of Abu Dhabi. *Saudi Journal of Kidney Diseases And Transplantation* .26(5),1028-1034.doi:105001/omj.2013.99.
52. Robert ,A Star. (2015) Treatment of acute renal failure. *International Journal of Kidney*, 54.1817-1831.doi:10.1046/j.1523-1755.19980020.
53. Silva et al. (2013). Physical therapy during haemodialysis in patients with chronic kidney disease. *Brazilian Journal of Nephrology*.35(3),158-160.doi:10.5935/0101-2800020130028.
54. Singh et al. (2014).Prevalence of chronic kidney disease among adults in a rural community in South India. *Indian Journal of Nephrology*.24 (4),214-222.doi:10.4103/0971-4065.132990.

55. Sunder, Rao. (1996). An introduction to biostatistics. 11th edition. Vellore: Orient Longman Publication.
56. Varma, PP.(2015). Prevalence of chronic kidney disease in India . *Indian Journal of Nephrology*.25(3),133-135.
57. William L Henrich.(2009). Principles and practice of dialysis. 4th edition. Philadelphia: Lippincott Publication.

ANNEXURE-I

PERMISSION LETTER

FROM

LEKHA.J

I YEAR M.Sc NURSING

PSG COLLEGE OF NURSING

PEELAMEDU

COIMBATORE-4

TO

Dr. G.VENU MD DM

DEPARTMENT OF NEPHROLOGY

HEAD OF THE DEPARTMENT

PSG HOSPITALS

COIMBATORE-4

THROUGH

THE PRINCIPAL

PSG COLLEGE OF NURSING

Respected Sir

SUBJECT: Seeking permission to carry out the study in Dialysis unit PSG Hospitals, Coimbatore.

I Lekha.J I year M.Sc Nursing student is interested in doing this study. "A study to assess the effectiveness of Intradialytic Stretching Exercises on Prevention and Reduction of Muscle Cramps among Patients undergoing Hemodialysis at PSG Hospitals, Coimbatore". kindly grant me permission to carry out the study.

Thanking You

Date: 6-2-19

Place: PSG Hospitals

Yours sincerely

(Lekha.J) J. Lekha

Signature of Medical Guide:
Dr. G. VENU MD DM
Reg. No. 46379
Professor of Nephrology
Department of Nephrology
PSG IMSR & Hospitals
COIMBATORE - 4.

PERMISSION LETTER

FROM

LEKHA.J

I YEAR M.Sc NURSING

PSG COLLEGE OF NURSING

PEELAMEDU

COIMBATORE-4

TO

Dr. VIMAL KUMAR GOVINDAN

MEDICAL DIRECTOR

PSG HOSPITALS

COIMBATORE-4

THROUGH

THE PRINCIPAL

PSG COLLEGE OF NURSING


64/02/2015

Respected Sir

SUBJECT: Seeking permission to carry out the study in Dialysis unit PSG Hospitals, Coimbatore.

I Lekha.J I year M.Sc Nursing student is interested in doing this study. "A study to assess the effectiveness of Intradialytic Stretching Exercises on Prevention and Reduction of Muscle Cramps among Patients undergoing Hemodialysis at PSG Hospitals, Coimbatore". kindly grant me permission to carry out the study.

Thanking You

Date: 04.02.15

Place: PEELAMEDU

Yours sincerely

(Lekha.J) J. Lekha

Signature of Medical Director:


Dr. Vimal Kumar Govindan, MS, FRCSed.,
Medical Director
PSG Hospitals
Peelamedu,
Coimbatore - 641 004.

ANNEXURE-II



PSG Institute of Medical Sciences & Research Institutional Human Ethics Committee

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)

POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA

Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

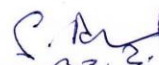
Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every 12 months
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
 - a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
 - b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
 - c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval
 - d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented
 - e. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented
 - f. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within the stipulated period for review
7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

Kindly note this approval is subject to ratification in the forthcoming full board review meeting of the IHEC.

Thanking You,

Yours Sincerely,



Dr S Bhuvaneshwari
Member - Secretary
Institutional Human Ethics Committee





PSG Institute of Medical Sciences & Research

Institutional Human Ethics Committee

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)

POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA

Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

To
Ms Lekha J
I M Sc Nursing
PSG College of Nursing
Coimbatore

Ref: Project No.15/089

Date: March 30, 2015

Dear Ms Lekha,

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application dated 18.02.2015 to conduct the research study entitled "A study to assess the effectiveness of intradialytic stretching exercises on prevention and reduction of muscle cramps among patients undergoing hemodialysis at PSG Hospitals, Coimbatore" during the IHEC meeting held on 27.02.2015.

The following documents were reviewed and approved:

1. Project Submission form
2. Study protocol
3. Informed consent form
4. Data collection tool
5. Permission letter from concerned Head of the Departments
6. Current CVs of Principal investigator, Co-investigator
7. Budget

The following members of the Institutional Human Ethics Committee (IHEC) were present at the meeting held on 27.02.2015 at IHEC Secretariat, PSG IMS & R between 10.00 am and 11.00 am:

Sl. No.	Name of the Member of IHEC	Qualification	Area of Expertise	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1	Dr. P. Sathyan (Chairperson, IHEC)	DO, DNB	Clinician (Ophthalmology)	Male	No	Yes
2	Dr. S. Bhuvaneshwari (Member-Secretary, IHEC)	MD	Clinical Pharmacology	Female	Yes	Yes
3	Dr. S. Shanthakumari	MD	Pathology, Ethicist	Female	Yes	Yes
4	Dr. D. Vijaya	M Sc, Ph D	Basic Medical Sciences (Biochemistry)	Female	Yes	Yes

The study is approved in its presented form. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.

ANNEXURE-III

**PSG Institute of Medical Science and Research, Coimbatore
Institutional Human Ethics Committee
INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS**

(strike off items that are not applicable)

I Lekha.J , am carrying out a study on the topic: "A STUDY TO ASSESS THE EFFECTIVENESS OF INTRADIALYTIC STRETCHING EXERCISES ON PREVENTION AND REDUCTION OF MUSCLE CRAMPS AMONG PATIENTS UNDERGOING HEMODIALYSIS AT PSG HOSPITALS, COIMBATORE".

as part of my research project being carried out under the aegis of the Department of:Nursing.

My research guide is: Dr. Elizabeth Jean Abraham, Principal PSG College of Nursing / Dr.G.Malarvizhi, Vice Principal PSG College of Nursing

The justification for this study is:Muscle cramps are commom discomfort experienced by patients undergoing haemodialysis. Many non pharmacological therapies are employed by patients prior to treatment, but there is only a little evidence to support the use of non pharmacological measures.

The objectives of this study are:

- Primary Objective: Assess the level of muscle cramps among patients undergoing hemodialysis.
- Secondary Objective: Evaluate the effect of intradialytic stretching exercises on muscle cramps during hemodialysis

Sample size: 60

Study volunteers / participants are (specify population group & age group): Patients undergoing hemodialysis

Location: PSG Hospitals, Coimbatore

I request you to kindly cooperate with us in this study. We propose collect background information and other relevant details related to this study. We will be carrying out:

Data collected will be stored for a period of 5 years. We will / will not use the data as part of another study.

Benefits from this study: Intradialytic stretching exercises prevent and reduce the muscle cramps among patients undergoing Hemodialysis.

Projected outcome: Intradialytic stretching exercises could prevent and reduce the muscle cramps among patients undergoing haemodialysis.

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date:

Witness:

Contact number of PI:8903474648

Contact number of Ethics Committee Office: 0422 2570170 Extn.: 5818

INFORMED CONSENT

The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator/s. Having understood the same, I hereby give my consent to them to interview me. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements).

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date:

Witness:

Contact number of PI: 8903474648

Contact number of Ethics Committee Office: 0422 2570170 Extn.: 5818

ஓப்புதல் படிவம்

தேதி :

ஜா. லேகா, ஆகிய நான், பி. எஸ். ஜி. மருத்துவக் கல்லூரியின், செவிலியர் துறையின் கீழ், “இரத்த ஊடுசிகிச்சை மேற்கொள்ளும் நோயாளிகளின் தசைப்பிடிப்பு பிரச்சனையை குறைத்தல் மற்றும் தடுப்பதற்கான தசைநீட்சி உடற்பயிற்சியின் திறனை கண்டறிவதற்கான ஆய்வு” என்ற தலைப்பில் ஆய்வு மேற்கொள்ள உள்ளேன்.

என் ஆய்வு வழிகாட்டி: டாக்டர். எலிசபெத் ஜீன் ஆப்ரகாம்

ஆய்வு மேற்கொள்வதற்கான அடிப்படை:

இரத்த ஊடுசிகிச்சை மேற்கொள்வோர்களில் 33-86 சதவீதம் நோயாளிகளுக்கு இந்த தசைப்பிடிப்பு என்ற பின்விளைவு ஏற்படுவதை காணலாம். தற்பொழுது இதற்கான சிகிச்சை முறைகள் மிகவும் பாதுகாப்பானது மற்றும் அதிகபலன் அளிக்கக்கூடியது என்றும் நிரூபனம் செய்யப்பட்டுள்ளது.

ஆய்வின் நோக்கம்:

- இரத்த ஊடுசிகிச்சையின்போது நோயாளிகளுக்கு ஏற்படும் தசைப்பிடிப்பின் அளவை அல்லது நிலையை கண்டறிதல்.
- இரத்த ஊடுசிகிச்சையின்போது தசைப்பிடிப்பிற்கான தசைநீட்சி உடற்பயிற்சியின் திறனை மதிப்பிடுதல்.

ஆய்வில் பங்கு பெறும் நபர்களின் எண்ணிக்கை: 60

ஆய்வு மேற்கொள்ளும் இடம்: பி. எஸ். ஜி. மருத்துவமனை, கோயம்புத்தூர்.

ஆய்வின் பலன்கள்:

இரத்த ஊடுசிகிச்சை நோயாளிகளுக்கு அளிக்கப்படும் பயிற்சி முறைகளிலேயே தசைநீட்சி உடற்பயிற்சி தசைப்பிடிப்பை குறைக்கும் மற்றும் தசைப்பிடிப்பிலிருந்து பாதுகாப்பளிக்கும்.

ஆய்வினால் ஏற்படும் அசௌகரியங்கள் / பக்க விளைவுகள்: பக்க விளைவுகள் எதுவும் இல்லை.

இந்த ஆய்வில் கிடைக்கும் தகவல்கள் 5 வருடங்கள் பாதுகாக்கப்படும். இவை வேறு எந்த ஆய்விற்கும் பயன்படுத்தப்பட மாட்டாது. எந்த நிலையிலும் உங்களைப் பற்றிய தகவல்கள் யாருக்கும் தெரிவிக்கப்படமாட்டாது. அவை இரகசியமாக வைக்கப்படும்.

எந்த நேரத்தில் வேண்டுமானாலும் ஆய்விலிருந்து விலகிக்கொள்ளும் உரிமை உங்களுக்கு உண்டு. ஆய்விலிருந்து விலகிக்கொள்வதால் உங்களுக்கு அளிக்கப்படும் சிகிச்சையில் எந்த வித மாற்றமும் இருக்காது.

இந்த ஆராய்ச்சிக்காக உங்களிடம் சில கேள்விகள் கேட்கப்படும் / சில இரத்த மாதிரிகள் அல்லது திசு மாதிரிகள் எடுக்கப்படும்.

மேலும், இந்த ஆய்வில் பங்கு கொள்வது உங்கள் சொந்த விருப்பம். இதில் எந்த விதக் கட்டாயமும் இல்லை. நீங்கள் விருப்பப் பட்டால், இந்த ஆய்வின் முடிவுகள் உங்களுக்குத் தெரியப் படுத்தப்படும்.

ஆய்வாளரின் கையொப்பம் :

தேதி :

நோயாளிகளின் தகவல் படிவம்

நான் இந்த ஆராய்ச்சியின் நோக்கம் மற்றும் அதன் பயன்பாட்டினைப் பற்றி தெளிவாகவும், விளக்கமாகவும் தெரியப்படுத்தப் பட்டுள்ளேன். இந்த ஆராய்ச்சியில் பங்கு கொள்ளவும், இந்த ஆராய்ச்சியின் மருத்துவ ரீதியான குறிப்புகளை வரும் காலத்திலும் உபயோகப்படுத்திக் கொள்ளவும் முழு மனதுடன் சம்மதிக்கிறேன்.

ஆய்வுக்குட்படுபவரின் பெயர், முகவரி:

கையொப்பம்:

தேதி:

ஆய்வாளரின் தொலைபேசி எண்: 8903474648

மனித நெறிமுறைக் குழு அலுவலகத்தின் தொலைபேசி எண்: 0422 2570170 Extn.: 5818

ANNEXURE IV

INSTRUMENTS AND TOOL FOR DATA COLLECTION

SECTION: A

Part A

Demographic Data:

1. Sample No:
2. Age in years:
3. Gender :
4. Diagnosis:
5. Duration of illness:
5. Number of Hemodialysis:
6. Education:
7. Occupation:

Part B

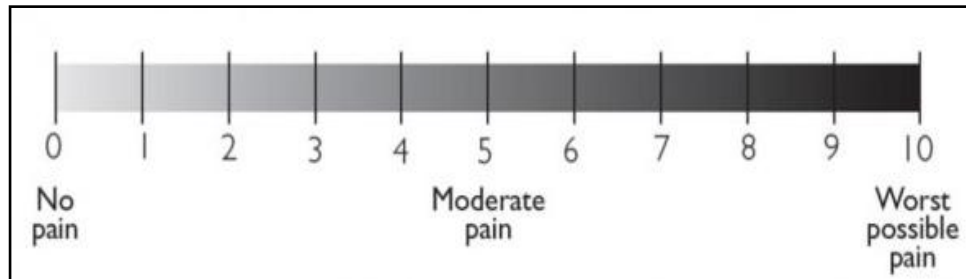
Clinical Variable:

1. What is the duration of your dialysis treatment?
a) Days
b) Month
c) Years
2. How many hours you are being on dialysis in a day?
a) 4 hours
b) 6 hours
c) 8 hours
3. How many sittings of hemodialysis do you have in a week?
a) Once
b) Twice
c) Thrice

4. If yes, when do you experience the muscle cramps during hemodialysis?
- a) First hour
 - b) Middle hour
 - c) Last hour
5. Do the muscle cramps restrict your activities and movements during hemodialysis?
- a) Yes
 - b) No
6. In which leg do you experience muscle cramps?
- a) Right Leg
 - b) Left Leg
 - c) Both Leg
7. Where do you feel the cramps?
- a) Calf
 - b) Hamstring
 - c) Soleus
8. Have you been diagnosed with medical condition?
- a) Diabetes mellitus
 - b) Peripheral arterial disease
 - c) Cirrhosis of liver
 - d) Neurological disorder
 - e) Any other
9. Has your quality of life deteriorated because of muscle cramps?
- a) Very much
 - b) Somewhat
 - c) Not at all

SUBJECTIVE ASSESSMENT OF PAIN

VISUAL ANALOGUE SCALE:



CRAMP QUESTIONNAIRE CHART

S.NO	Feature of muscle cramps	Scores	Post test I	Post test II	Post test III
I	Frequency of cramps				
1	Does not occur	0			
2	Cramps occur less than 3 times /hour	1			
3	Cramps occur more than 3 times /hour	2			
II	Duration of the cramps				
1	Cramps does not occur	0			
2	Cramps lasts for less than 5 minutes	1			
3	Cramps lasts for more than 5 minutes	2			
III	Level of pain (VAS)				
1	No pain	0			
2	Pain 1-3	1			
3	Pain 4-6	2			
4	Pain 7-10	3			
IV	Temperature - Leg				
1	Warm	0			
2	Cold	1			
3	Cold /clammy	2			
V	Discomfort				
1	No cramps	0			
2	Perceptible	1			
3	Sensitive	2			
4	Painful	3			
5	Unbearable	4			

Score Interpretation:

- 0 No cramps
- 1-4 Mild cramps
- 5-8 Moderate cramps
- 9-13 Severe cramps

செய்தி சேகரிப்பதற்கான கருவிகள்

தொகுதி அ:

பகுதி அ: புள்ளிவிவர ஆய்வு செய்திகள்

பகுதி ஆ: மருத்துவமனை சார்ந்த கேள்விகள்

தொகுதி ஆ: தசைபிடிப்பு கேள்விகளுடன் கூடிய அட்டை மற்றும் பார்வை நிகழ்ச்சி

அளவுகோலினை பயன்படுத்தி தசைப்பிடிப்பினை அளவிடுதல்

தொகுதி :அ

பகுதி :அ

புள்ளிவிவர ஆய்வு செய்திகள்:

1. மாதிரி எண்:
2. வயது:
3. பாலினம்:
4. தீர்மானிக்கப்பட்ட நோய்:
5. நோய் இருக்கும் காலஅளவு:
6. இரத்தஊடுசிகிச்சையின் எண்ணிக்கை:
7. கல்வித்தகுதி:
8. தொழில்:

பகுதி - ஆ





1. நீங்கள் எவ்வளவு காலமாக இரத்தஊடுசிகிச்சை பெற்று வருகிறீர்கள்?
அ. நாட்களாக ஆ. மாதங்களாக இ. வருடமாக
2. உங்களுக்கு இரத்தஊடுசிகிச்சை எத்தனை மணி நேரம் நடைபெறும்?
அ. 4 மணி நேரம் ஆ. 6 மணி நேரம் இ. 8 மணி நேரம்
3. ஒரு வாரத்திற்கு எத்தனை முறை இரத்தஊடுசிகிச்சை பெற்று வருகிறீர்கள்?
அ. ஒரு முறை ஆ. 2 முறை இ. 3 முறை
4. தசைப்பிடிப்பு பிரச்சனை எப்பொழுது ஏற்படும்?
அ. முதல் மணி நேரத்தில் ஆ. இடைப்பட்ட நேரத்தில் இ. இறுதிகட்ட நேரத்தில்
5. தசைப்பிடிப்பு பிரச்சனை ஏற்படும் பொழுது வேறு இயக்க பிரச்சனை ஏற்படுகிறதா?
அ. ஆம் ஆ. இல்லை
6. தசைப்பிடிப்பு பிரச்சனை எந்த காலில் ஏற்படுகிறது?
அ. வலது கால் ஆ. இடது கால் இ. இரண்டு காலிலும்
7. உங்களுக்கு காலில் எந்த பகுதியில் தசைப்பிடிப்பு பிரச்சனை ஏற்படுகிறது?
அ. கெண்டை கால் பகுதி ஆ. தொடை பகுதி இ. விரல் பகுதி
8. உங்களுக்கு மருத்துவ பிரச்சனை உள்ளதா?
அ. சர்க்கரை நோய் ஆ. இரத்த குழாய் பிரச்சனை இ. கல்லீரல் வீக்க நோய்
அ. நரம்பியல் நோய் உ. வேறு ஏதாவது?
9. தசைப்பிடிப்பு பிரச்சனையால் உங்கள் வாழ்க்கை தரம் பாதிக்கப்படுகிறதா?
அ. மிகவும் ஆ. சில சமயம் இ. இல்லவே இல்லை.



தசைப்பிடிப்பு அம்சங்கள்

வ.எண்	தசைப்பிடிப்பு அம்சங்கள்	மதிப்பெண்
1	தசைப்பிடிப்பு ஏற்படும் முறைகள்	
அ	தசைப்பிடிப்பு ஏற்படாது	0
ஆ	தசைப்பிடிப்பு 3 முறைக்கு குறைவாக ஏற்படும்	1
இ	தசைப்பிடிப்பு 3 முறைக்கு அதிகமாக ஏற்படும்	2
2	தசைப்பிடிப்பு ஏற்படும் கால அளவு	
அ	ஏற்படாது	0
ஆ	தசைப்பிடிப்பு 5 நிமிடத்திற்கு குறைவாக ஏற்படும்	1
இ	தசைப்பிடிப்பு 5 நிமிடத்திற்கு அதிகமாக ஏற்படும்	2
3	வலியின் கால அளவு	
அ	வலி இல்லை	0
ஆ	வலியின் கால அளவு 1-3	1
இ	வலியின் கால அளவு 4-6	2
ஈ	வலியின் கால அளவு 7-10	3
4	உடல் வெப்பநிலை	
அ	வெதுவெதுப்பாக	0
ஆ	குளுமையாக	1
இ	குளுமை (அ)	2
5	தசைப்பிடிப்பினால் ஏற்படும் அசௌகரியங்கள்	
அ	தசைப்பிடிப்பு ஏற்படாது	0
ஆ	தசைப்பிடிப்பு ஏற்படுவதற்கான அறிகுறிகள் ஏற்படும்	1
இ	தசைப்பிடிப்பினை உணர முடியும்	2
ஈ	வலி இருக்கும்	3
உ	தாங்க முடியாது	4

ANNEXURE V

INTRADIALYTIC STRETCHING EXERCISES

Sl.No	Exercise	Description	Picture
1	Ankle Dorsiflexion	<ul style="list-style-type: none"> Place the non dominant hand over the knee to stabilize the knee Place the dominant hand under the heel, with the foot against the forearm, and push the heel downward with this hand. Hold the position for 20-30 seconds. Repeat the action for 5 times. 	
2	Gastrocnemius-Passive Stretch	To stretch one muscle (the gastrocnemius), extend the knee, place the other hand on top of the ankle, and push in the opposite direction	
3	Soleus-Passive Stretch	To stretch the second muscle (the soleus), flex the knee, place the other hand under the calf, and push in the opposite direction.	
4	Hamstring Stretching	METHOD 1 <ul style="list-style-type: none"> Kneel between the legs and support the ankle with your arm or shoulder. The knee will be straight. Place one or both hands just above your knee, stabilizing the hip joint. Raise the leg straight up to approximately 90 degrees. Hold it for 20-30 seconds. Repeat the action for 5 times. 	

		<p>METHOD 2</p> <ul style="list-style-type: none"> • Place one hand under the knee and the other hand under the heel. • With the knee straight and the kneecap pointed toward the ceiling, raise the whole leg toward the ceiling. • When the raised knee begins to bend slightly, the hand under your knee should be moved to the top of your knee. 	
5	Quadriceps Stretch	<ul style="list-style-type: none"> • Flex the knee of the patient until the heel touches his back. • Place the non –dominant hand over the pelvis to restrict the pelvic rotation. • Hold the flexed knee on the hands and try to extend the hip as much as possible. • Hold the position for 20-30 minutes and relaxes. • Repeat the procedure for 5 times. 	

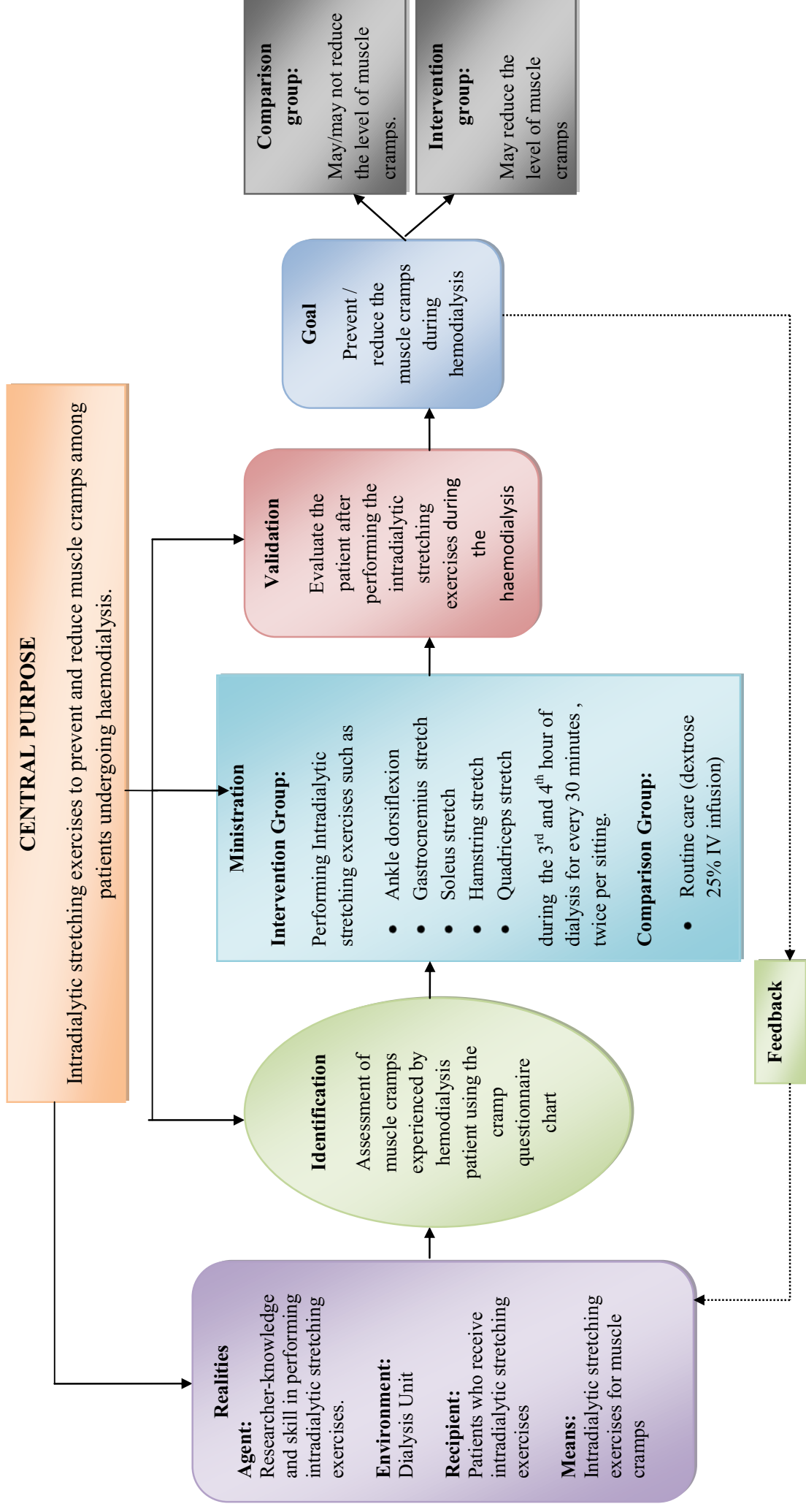


Figure 1.1: Modified Widenbach's Helping Art of Clinical Nursing Theory to Assess the Effectiveness of Intradialytic Stretching Exercises on Prevention and Reduction of Muscle Cramps

..... Not included in the study